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I. BACKGROUND

Plaintiff alleges infringement of United States Patent No. 5,817,364 (“the ‘364 patent”) in this lawsuit. The application leading to the ‘364 patent is based on a PCT application filed on November 8, 1994, which is based on an application filed in Sweden on November 9, 1993. The ‘364 patent issued on October 6, 1998, and is entitled “Beverage Containing Alpha-Ketoglutaric Acid and Method of Making.” In general, the ‘364 patent is directed to an energy beverage that comprises α -ketoglutaric acid, or a water-soluble innocuous salt thereof, for situations which demand a large and rapid energy supply to a healthy mammal. The Abstract of the ‘364 patent states:

The present invention is related to an energy supply composition particularly suitable for use before, during and after physical exertion. The composition is a beverage, or a dry composition therefore, useful as an energy source in situations which demand a large and rapid energy supply to a healthy mammal including man. The beverage comprises an effective amount of alpha-ketoglutaric acid or a water-soluble innocuous salt thereof together with a nutritionally acceptable water-soluble carrier.

Representative claims of the ‘364 patent are shown below:

1. A beverage, or a dry composition therefor, providing an energy source in situations with demand of large and rapid energy supply to a healthy mammal comprising 0.1 to 2.5 percent of the wet weight of α -ketoglutaric acid or a water-soluble innocuous salt thereof together with a nutritionally acceptable water-soluble carrier.
2. A beverage, or a dry composition therefor, according to claim 1, wherein α -ketoglutaric acid is combined with malic acid.
7. A method of large and rapid energy supply to a healthy mammal, comprising providing to said animal, a beverage, or a dry composition therefor, comprising 0.1 to 2.5 percent of the wet weight of α -ketoglutaric acid or a water-soluble innocuous salt thereof together with a nutritionally acceptable water-soluble carrier.

Of relevance to this opinion and the parties' dispute as to certain terms of the '364 patent, previous defendant USPlabs, LLC filed a request for inter partes reexamination with the Patent Trial and Appeal Board ("PTAB") on July 12, 2013 on claims 1-7 of the '364 patent. (*See, e.g.*, Exh. 191-5 at 921-974.) On November 15, 2013, the PTAB denied the petition to institute an inter partes reexamination and found that "USPlabs has not shown that there is a reasonable likelihood that it will prevail with respect to at least one of the challenged claims, and the petition is denied." (*See USPlabs, LLC v. Harcol Res., LLC*, No. IPR2013-00399, 1 (P.T.A.B. Nov. 15, 2013) ("PTAB Opinion"), found at Dkt. No. 191-5 at 990-1000.) The PTAB Opinion is relevant to both parties' claim construction arguments.

II. LEGAL PRINCIPLES

"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) (en banc) (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). To determine the meaning of the claims, courts start by considering the intrinsic evidence. *See id.* at 1313; *see also C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 861 (Fed. Cir. 2004); *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). The intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *See Phillips*, 415 F.3d at 1314; *C.R. Bard*, 388 F.3d at 861. Courts give claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention in the context of the entire patent. *Phillips*, 415 F.3d at 1312-13; *accord Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003).

The claims themselves provide substantial guidance in determining the meaning of particular claim terms. *Phillips*, 415 F.3d at 1314. First, a term’s context in the asserted claim can be very instructive. *Id.* Other asserted or unasserted claims can aid in determining the claim’s meaning because claim terms are typically used consistently throughout the patent. *Id.* Differences among the claim terms can also assist in understanding a term’s meaning. *Id.* For example, when a dependent claim adds a limitation to an independent claim, it is presumed that the independent claim does not include the limitation. *Id.* at 1314-15.

“[C]laims ‘must be read in view of the specification, of which they are a part.’” *Phillips*, 415 F.3d at 1315 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc)). “[T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); accord *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). This is true because a patentee may define his own terms, give a claim term a different meaning than the term would otherwise possess, or disclaim or disavow claim scope. *Phillips*, 415 F.3d at 1316. In these situations, the inventor’s lexicography governs. *Id.* The specification may also resolve the meaning of ambiguous claim terms “where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone.” *Teleflex*, 299 F.3d at 1325. But, “[a]lthough the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.” *Comark Commc’ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998) (quoting *Constant v.*

Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed. Cir. 1988)); accord *Phillips*, 415 F.3d at 1323.

The prosecution history is another tool to supply the proper context for claim construction because a patent applicant may also define a term in prosecuting the patent. *Home Diagnostics, Inc., v. Lifescan, Inc.*, 381 F.3d 1352, 1356 (Fed. Cir. 2004) (“As in the case of the specification, a patent applicant may define a term in prosecuting a patent.”). “[T]he prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance.” *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985).

Although extrinsic evidence can be useful, it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Phillips*, 415 F.3d at 1317 (citations and internal quotation marks omitted). Technical dictionaries and treatises may help a court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but technical dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *Id.* at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert’s conclusory, unsupported assertions as to a term’s definition are entirely unhelpful to a court. *Id.* Generally, extrinsic evidence is “less reliable than the patent and its prosecution history in determining how to read claim terms.” *Id.*

The “determination of claim indefiniteness is a legal conclusion that is drawn from the Court’s performance of its duty as the construer of patent claims.” *Exxon Research & Eng’g Co.*

v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Section 112 entails a “delicate balance” between precision and uncertainty:

On the one hand, the definiteness requirement must take into account the inherent limitations of language. Some modicum of uncertainty, the Court has recognized, is the price of ensuring the appropriate incentives for innovation. ... At the same time, a patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them. Otherwise there would be a zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims. And absent a meaningful definiteness check, we are told, patent applicants face powerful incentives to inject ambiguity into their claims. ... Eliminating that temptation is in order, and the patent drafter is in the best position to resolve the ambiguity in patent claims.

Nautilus Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2128-29 (2014) (citations omitted). Therefore, in order for a patent to be definite under § 112, ¶2, “a patent’s claims, viewed in light of the specification and prosecution history, [are required to] inform those skilled in the art about the scope of the invention with reasonable certainty.” *Id.* at 2129. The determination of “definiteness is measured from the viewpoint of a person skilled in the art at the time the patent was filed.” *Id.* at 2128. (emphasis original, citations omitted). “The definiteness requirement . . . mandates clarity, while recognizing that absolute precision is unattainable.” *Id.* This standard reflects rulings that have found that “the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.” *Id.* at 2129. “Whether a claim reasonably apprises those skilled in the art of its scope is a question of law that [is] review[ed] de novo.” *Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1374 (Fed. Cir. 2008). As it is a challenge to the validity of a patent, the failure of any claim in suit to comply with § 112 must be shown by clear and convincing evidence. *Nautilus*, 134 S. Ct. at n.10.

III. CONSTRUCTION OF AGREED TERMS

The Court notes the following agreed constructions:

| <u>Term</u> | <u>Agreed Construction</u> |
|---|-----------------------------|
| “nutritionally acceptable water-soluble carrier” (claims 1, 5, 7) | Plain and ordinary meaning. |
| “providing to” (claim 7) | Plain and ordinary meaning. |

(Dkt. No. 181, 06/10/2014 Joint Claim Construction and Prehearing Statement.)

IV. CONSTRUCTION OF DISPUTED TERMS

The parties’ positions and the Court’s analysis as to the disputed terms are presented below.

A. “large and rapid energy supply”

| <u>Term</u> | <u>Plaintiff’s Proposed Construction</u> | <u>Defendants’ Proposed Construction</u> |
|--|--|--|
| “large and rapid energy supply” (claims 1 and 7) | This isolated term should be given its plain and ordinary meaning. In context, it should be construed as indicated above, see “providing an energy source in situations with demand of large and rapid energy supply to a healthy mammal (Claim 1)” and “method of large and rapid energy supply to a healthy mammal (Claim 7).” | Indefinite. |
| “situations with demand of large and rapid energy supply” (claim 1) | Athletic performance. See “providing an energy source in situations with demand of large and rapid energy supply to a healthy mammal (Claim 1)” above. | Indefinite. |

The disputed term “large and rapid energy supply” appears in claims 1 and 7 of the ‘364 patent, but is used in very different ways in each. The phrase “situations with demand of large

and rapid energy supply” appears in only claim 1 of the ‘364 patent. The phrase “a method of large and rapid energy supply” appears only in claim 7.

(1) The Parties’ Positions

Plaintiff submits that these phrases are not indefinite because they can be understood by one of ordinary skill in the art. (*See, e.g.*, Dkt. No. 191 at 14-15.) Plaintiff argues that they are not indefinite because the USPTO never found they were indefinite during prosecution and the petition for inter partes review. (*Id.*) For the “large and rapid energy supply” term, the Plaintiffs argue that it simply carries its plain and ordinary meaning. (*Id.* at 14.) For the “situations with demand of large and rapid energy supply” term, the Plaintiffs argue the specification implies that the term means “athletic performance.” (*Id.* at 15.)

Defendants responds that a person of ordinary skill in the art would not know what a “large and rapid energy supply” is in this context, there is no standard meaning for this term, and there is no meaning to this term provided in the intrinsic record. (*See, e.g.*, Dkt. No. 195 at 6-7.) Defendants argue that “large” can have several meanings and there is no indication in the specification or the prosecution history what is the intended meaning in the claims of the ‘364 patent. (*Id.* at 7.) Defendants argue that “large” can refer to the amount or quantity of energy in comparison to another amount or quantity of energy, or it can refer to the amount of time for which an energy supply is required; however, the specification does not provide any guidance as to which meaning applies or the relevant quantities of time or energy. (*Id.*) Defendants also argue that a person of ordinary skill in the art at the relevant time would surmise that the phrase “rapid energy supply” would have multiple possible meanings depending upon whether it refers to how rapidly the energy is utilized or how rapidly the energy is stored. (*Id.* at 9.) Defendants argue that the distinction between these two possible meanings is significant because they are

opposites - if the phrase means rapidly utilizing, then the energy is consumed quickly, but if the phrase means rapid storage, then the energy is not consumed. (*Id.*) Defendants further argue that the specification makes the term even more ambiguous because it refers to both rapid energy utilization and rapid energy storage. (*Id.*) Further, Defendants argue that one of ordinary skill would not recognize the claimed beverage as providing a large and rapid energy supply, since what may be a “large” or “rapid” energy supply for one functionality of α -ketoglutaric acid may not be “large” or “rapid” for another functionality. (*Id.* at 10-11.)

Plaintiff replies that the phrase “large and rapid energy supply” in context means one that will provide energy before, during, and after physical exertion. (*See, e.g.*, Dkt. No. 197 at 3.) Plaintiffs argues that to a person having ordinary skill in the art, a “large . . . energy supply” is the amount of energy needed to participate in physical exertion or stressful physical exercise on a daily basis. (*Id.* at 4.) Plaintiffs argue that to a person having ordinary skill in the art, the “rapid energy supply” term means “energy supplied as it is needed during physical exertion, or in order to engage in stressful physical exercise.” (*Id.* at 4.) Plaintiff argues that the term “rapid” is comparative referring to how soon the invention acts after consumption. (*Id.* at 4-5.) Plaintiff argues that, as a whole, the disputed term “large and rapid energy supply” means that the amount of energy supplied via the α -ketoglutaric acid is the amount necessary to perform physical exertion or stressful physical exercise, such as a six-kilometer run, 50-60 sit-ups or 30-40 pushups—and is rapid in that, having drank the beverage daily, the body was able to respond to the physical exertion or physical exercise quickly. (*Id.* at 5.)

(2) Analysis

The specification provides various references to the “science” of metabolism and how the alpha-ketoglutaric acid of the claimed invention allegedly operates. The ‘364 patent teaches that

the “present invention is related to an energy supply composition particularly suitable for use before, during, and after physical exertion.” (‘364 patent, col. 1, ll. 6-8.) Other portions of the specification also teach that the disclosed beverage provides benefits before, during, and after physical exertion. (*Id.* at col. 4, ll. 65-67, col. 5, ll. 38-41, ll. 59-60.) The ‘364 patent teaches that the invention provides both rapid energy utilization and rapid energy storage and also provides retained endurance:

The object of the invention is to **facilitate extended physical exertion** by providing energy that is efficiently utilized in mammals. A further object of the invention is to facilitate the accretion of muscle tissue as a result of physical training by sustaining an adequate energy status and permitting rapid build-up of the body’s stored energy levels upon rest. A further object is to reduce the loss of water from the body during physical exertion by retaining a high rate of water absorption in the gastrointestinal tract from an energy rich beverage.

The beverage of the present invention provides energy according to the principle of **rapid energy recruitment** within the organelles of the mammalian cell. An organelle is a sub-cellular compartment representing specialized metabolic function, such as the mitochondria where the formation of energy by oxidative reaction in the citric acid cycle takes place. (See citric acid cycle, FIG. 2). The main energy substrate of the said beverage, α -ketoglutaric acid, **is rapidly converted to energy or other metabolites**, such as glucose, and a minimum of metabolic waste products. Further, α -ketoglutaric acid stimulates the transport of glucose from the blood into the muscle. **The invention will thereby enhance the performance of muscle fibres and save or replenish the indigenous energy depot resulting in an enhanced physical and mental endurance.** Also, α -ketoglutaric acid, a constituent in the gluconeogenesis, increases the glycogen deposition when administered before exertion, **leading to improved exercise endurance.**

α -ketoglutaric acid is formed in each cell that is active in terms of oxidative metabolism and/or amino acid deamination reactions, and is therefore not considered as an essential nutrient. The cells of the intestinal mucosa utilize α -ketoglutaric acid, derived from glutamine, as an energy substrate. This reaction has not, until now, been considered to be limiting for an optimal intestinal function in healthy individuals. Athletes consuming two to four times as much calories as the untrained person, have not been thoroughly studied from such aspect. A further advantage is provided by the invention on the intestinal function

exemplified by a sustained absorption efficiency during periods of large food intake, which permits a **rapid build-up of the body's stored energy** levels upon rest.

Taken together, the improved muscle energy and water supply during physical exertion and the sustained intestinal absorption during periods of large food intake, make the invention facilitate the accretion of muscle tissue as a result of physical training.

(*See, e.g.*, '364 patent, col. 1, ll. 9-18; col. 5, ll. 23-63)(emphasis added). The fact that the beverage may provide (in different situations) rapid energy utilization, rapid energy storage, and/or retained endurance does not necessarily make the phrase "large and rapid energy supply" contradictory or indefinite as Defendants claim.

The claim language controls, and the Court finds the patentee's different use of the phrase "large and rapid energy supply" in the different independent claims to be significant. While claim 1 recites "A beverage ... providing an energy source in situations with demand of large and rapid energy supply..." claim 7 recites "[a] method of large and rapid energy supply...comprising providing...a beverage..." Thus, pursuant to the express claim language, claim 7 relates to the supply of large and rapid energy through the claimed beverage itself, while claim 1 is directed to identifying situations demanding a large and rapid energy supply (such as physically exerting activities) in which the beverage will be used. Plaintiff's constructions for the different phrases in claims 1 and 7 confirm that there is a distinction in the claim language, and during the claim construction hearing Defendants agreed that there was a difference in the use of the disputed phrase between claims 1 and 7.

On balance, the Court finds that one of ordinary skill in the art would understand that the recitation of "providing an energy source in *situations with demand of large and rapid energy supply*" in claim 1 refers to the providing of an energy source (such as the claimed beverage) in

connection with physically exerting activities. Based on the language of claim 1, the energy beverage itself is not necessarily providing a certain amount or quantity of a “large and rapid energy supply,” but is rather being used in situations requiring such an energy supply. Based on the specification, it is clear that the claimed beverage is to be utilized in situations demanding significant physical exertion. (See, e.g., ‘364 patent, col. 1, ll. 6-18; col. 1, ll. 38-40; col. 3, ll. 28-38; col. 4, ll. 65-66; col. 5, ll. 59-63; col. 6, l. 64-col. 8, l. 25.) In particular, the specification teaches that “[i]ndividuals undergoing **significant physical exertion** whether for athletic or other purposes increase their nutritional needs substantially in order to maintain the body's energy storage and to develop its muscular capacity.” (*Id.* at col. 1, ll. 21-24)(emphasis added.) Thus, Defendants’ arguments related to the fact that the claimed beverage may provide in only some situations rapid energy utilization, rapid energy storage, and/or retained endurance (but not in all situations) does not provide any inherent conflict to the phrase “situations with demand of large and rapid energy supply” as that concept is used in claim 1. While the Court rejects Plaintiff’s construction of this phrase to mean merely “athletic performance,” the Court finds that the phrase “situations with demand of large and rapid energy supply” does mean “situations demanding significant physical exertion.” The Court finds this is clearly and repeatedly supported in the intrinsic record and gives sufficient clarity to the phrase and that one of ordinary skill in the art would understand activities that require a significant amount of physical exertion and activities that do not in the context of the ‘364 patent. Accordingly, pursuant to the Supreme Court’s holding in *Nautilus*, the Court rejects Defendants’ arguments that the claim when “read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.”

In contrast, however, the Court finds the phrase “[a] method of large and rapid energy supply to a healthy individual...” in claim 7 to be indefinite. The Defendants provide various arguments as to why there are multiple meanings to this phrase, why various definitions are inconsistent, and how the meanings may change based on different situations. While the Court does not find all of Defendants’ arguments compelling, the Court does agree with the Defendants that there is little to no guidance as to this term in the specification. Nor do Plaintiff’s arguments or the intrinsic support relied upon provide any significant meaning to the term “large and rapid energy supply” by itself. The fact that the beverage *may* be used before, during, or after physical activity does not necessarily mean that this phrase should be limited to all such uses or that the beverage must be taken on a daily basis – there are no requirements in the claim language for such limitations and to the extent Plaintiff argues such limitations, they are rejected. In contrast to claim 1, claim 7 is clear that the beverage itself is to supply a “large and rapid energy supply,” but it is unclear to one of ordinary skill how much that energy supply should be or what makes it a rapid supply of energy. While the Court is hesitant to find claims indefinite, for this situation the Court finds that, consistent with Defendant’s arguments, there is no dispute that one of ordinary skill in the art would not understand with “reasonable certainty” the scope of the invention and the bounds of claim 7. In particular, a person of ordinary skill in the art would not be able to determine with reasonable certainty what “large and rapid energy supply” is in the context of alpha-ketoglutaric acid. The intrinsic evidence is not helpful, nor are the moving constructions and arguments provided by Plaintiff.

The Court hereby construes “**situations with demand of large and rapid energy supply**” in claim 1 to mean “**situations demanding significant physical exertion.**”

The Court hereby finds “**A method of large and rapid energy supply**” in claim 7 to be indefinite.

B. “providing an energy source”

| <u>Plaintiff’s Proposed Construction</u> | <u>Defendants’ Proposed Construction</u> |
|--|--|
| <p>The isolated claim term should be construed in context with claim term “providing an energy source in situations with demand of large and rapid energy supply to a healthy mammal” and means “providing an energy supply composition particularly suitable for use before, during and after physical exertion to a healthy athlete and other healthy individual and, as applicable, another mammal individual who is not subject to inpatient or outpatient care for relevant conditions by a hospital or a medical or veterinary practitioner.”</p> | <p>Indefinite. In the alternative, plain and ordinary meaning.</p> |

The disputed term “providing an energy source” appears in claim 1 of the ‘364 patent.

(1) The Parties’ Positions

Plaintiff submits that the term is not indefinite and should be read in context of the surrounding claim language and not construed separately. (*See, e.g.*, Dkt. No. 191 at 18-20.)

Defendants respond that the term is indefinite because the intrinsic evidence provides no clear guidance on its meaning. (*See, e.g.*, Dkt. No. 195 at 12.) Defendants argue that there is no common understanding among those skilled in the art regarding what “providing an energy source” means because the phrase would be understood to have multiple meanings depending upon the type of activity being engaged in that requires an energy source. (*Id.*) For example, during an intense anaerobic activity such as sprinting, the term “providing an energy source” would be understood to mean providing glucose, specifically glucose that was previously stored in the muscles. (*Id.*) Thus, for an anaerobic activity, the energy source would have to be

provided sufficiently in advance of the activity in order to allow for the glucose to be stored in the muscle. (*Id.*) On the other hand, for lower intensity aerobic exercises, such as long distance running, the term “providing an energy source” would be understood to mean glucose and fat. (*Id.*) Defendants argue that nothing in the patent supports a conclusion that α -ketoglutaric acid actually provides an energy source. (*Id.*) While the specification describes α -ketoglutaric acid as the main energy substrate of the claimed beverage, the claimed beverages used for the Physical Tests contain ingredients such as glucose and fructose, which contribute to the overall energy content of the beverage. (*Id.* at 12-13.) Defendants argue that one of ordinary skill in the art would not consider the results of the Physical Tests in the ‘364 patent as evidence that the α -ketoglutaric acid within the claimed beverage provides an energy source. (*Id.* at 12.)

Plaintiff replies that, while there may not be a common understanding of this term, the term “providing an energy source” is readily understood based on the patent’s disclosures to mean “providing an energy supply composition particularly suitable for use before, during and after physical exertion.” (*See, e.g.*, Dkt. No. 197 at 5.) Plaintiff argues that its construction is consistent with the Abstract and specification. (*Id.*) Plaintiff argues that it is clear that the energy source of the invention is the composition comprising α -ketoglutaric acid. (*Id.*)

(2) Analysis

The disputed term “providing an energy source” appears in claim 1 of the ‘364 patent:

1. A beverage, or a dry composition therefor, **providing an energy source** in situations with demand of large and rapid energy supply to a healthy mammal **comprising 0.1 to 2.5 percent of the wet weight of α -ketoglutaric acid or a water-soluble innocuous salt thereof together with a nutritionally acceptable water-soluble carrier.**

(emphasis added.) It is clear that, in context, the claim covers a “beverage [] providing an energy source [] comprising 0.1 to 2.5 percent of the wet weight of α -ketoglutaric acid or a water-

soluble innocuous salt thereof together with a nutritionally acceptable water-soluble carrier.” In other words, the “providing an energy source ...” term is further defined by the subsequent language in the claim following “comprising.”

Defendants argue that the “providing an energy source” term is either indefinite or has its plain meaning. Defendants’ position largely rests on the argument that nothing in the ‘364 patent supports a conclusion that α -ketoglutaric acid actually provides an energy source. In other words, Defendants primarily do not dispute the meaning of the term or that it is “reasonably certain,” rather, they merely dispute the application of that term to the claimed structures and/or contend that the specification does not support the claim limitation. The Court finds that these are largely written description or enablement arguments, not indefiniteness arguments. This finding is confirmed by the fact that Defendants alternatively argue plain and ordinary meaning. It is unclear why the Plaintiff disputes the Defendants’ plain meaning construction. While the Plaintiff argues that the term should be construed with other disputed phrases and not construed separately, at times the Plaintiff appears to argue a plain meaning approach and that the disputed term is merely the claimed “composition comprising α -ketoglutaric acid.” Whether or not the specification sufficiently enables or describes a particular claim term is a validity argument – not a claim construction argument – and the Court will not address these separate issues at this time.¹

The Court finds that the “providing an energy source” term has no special meaning other than its plain meaning. *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343-44 (Fed. Cir. 2001) (generally terms are presumed to possess their ordinary meaning, although this can be overcome by statements of clear disclaimer). The Court rejects

¹ Likewise, the fact that the Court provides in this opinion a construction for a disputed term or that it holds a term has its plain meaning is not dispositive as to whether any term (construed or not construed) is necessarily supported by the ‘364 patent.

Plaintiff's argument that it needs a construction and Defendants' argument that it is indefinite. Further, the Court finds that the claim itself sufficiently describes the phrase a beverage "providing an energy source" as comprising "0.1 to 2.5 percent of the wet weight of α -ketoglutaric acid or a water-soluble innocuous salt thereof together with a nutritionally acceptable water-soluble carrier." Because this resolves the dispute between the parties, the Court finds that the term requires no further construction. See *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."); see also *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("[D]istrict courts are not (and should not be) required to construe every limitation present in a patent's asserted claims.") (citing *U.S. Surgical*, 103 F.3d at 1568).

Thus, the Court finds that there is no dispute that one of ordinary skill in the art would understand the meaning of the term "providing an energy source" in the context of the claimed invention. Likewise, the Court finds that there is no dispute that one of ordinary skill in the art would understand with "reasonable certainty" the scope of the invention and the bounds of the claims. Accordingly, pursuant to the Supreme Court's holding in *Nautilus*, the Court rejects Defendants' arguments that the claim when "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention."

The Court hereby construes "**providing an energy source**" to have its plain meaning.

C. “healthy mammal”

| <u>Plaintiff’s Proposed Construction</u> | <u>Defendants’ Proposed Construction</u> |
|--|---|
| “A healthy athlete and other healthy individual and, as applicable, another mammal individual who is not subject to inpatient or outpatient care for relevant conditions by a hospital or a medical or veterinary practitioner.” | Indefinite |

The disputed term “healthy mammal” appears in claims 1 and 7 of the ‘364 patent.

(1) The Parties’ Positions

Plaintiff submits that its construction is supported by the specification. (*See, e.g.*, Dkt. No. 191 at 16.) Plaintiff argues that during prosecution the patent was distinguished from prior art that related to treatment of critically ill patients as opposed to a healthy mammal including man. (*Id.*)

Defendants respond that while portions of the specification appear to attempt to define the term, the definitions are clearly inconsistent, and as a result, the patent fails to inform a person of ordinary skill with reasonable certainty about the scope of the invention. (Dkt. No. 195 at 13.) Defendants argue that while portions of the specification teach that a “healthy mammal” means one that is not being treated by a hospital or medical practitioner, the subsequent inclusion by the specification of “other individuals” and “convalescents” (which may be subject to in-patient or outpatient care) in the definition of “healthy mammal” creates ambiguity. (*Id.* at 14.) Because the patent and specification provide no basis to distinguish the status of individuals that are both included in and excluded from the classification of “healthy mammal” in the context of the patent, the term is indefinite. (*Id.*)

Plaintiff replies that Defendants’ manufactured confusion regarding the term “healthy mammal” is contradicted by the disclosures throughout the patent that define and provide context

to the term. (Dkt. No. 197 at 6.) Plaintiff argues that as demonstrated throughout the patent, a healthy mammal in this case, including a human, is one that is able to engage in physical exertion or strenuous physical exercise. (*Id.*) In particular, a healthy mammal is “a mammal whose metabolism is capable of metabolizing energy in a regular way, and therefore one who does not possess a medical condition that would preclude it from benefiting from the invention and would not be presented a unreasonable risk from the use of the invention.” (*Id.*) Plaintiff argues that the Defendants intentionally misinterpret the term “convalescent.” (*Id.* at 7.) The term “convalescent” means a person who is recovering from an illness or operation, not someone who is currently suffering from an illness, and even if the person is recovering, and subject to inpatient or outpatient care, Plaintiff argues that it does not mean that the person is “subject to inpatient or outpatient care for relevant conditions” as stated in Plaintiff’s construction. (*Id.*)

(2) Analysis

The parties’ primary dispute is whether the specification provides a definition to the term healthy mammal or whether there is so much ambiguity and/or inconsistency regarding this term that it is rendered indefinite.

The parties have advanced no arguments on whether the prosecution history or the claims are helpful to this dispute, and instead focus on the specification. The specification provides an entire paragraph related to the meaning of a “healthy mammal” as envisioned by the ‘364 patent:

In the last decades, so called sports beverages have enjoyed an increased use by athletes and others doing exercise. Such beverages have largely been based on sugars, salt, minerals and proteins and fragments thereof. For example, in Dialog Abstract No 02331774 (World Food & Drink Report, Oct. 19, 1989) a sports drink named GatorPro is described including water, glucose, soy protein isolate and soy oil. Various attempts have been made to provide a beverage, based on a sound scientific concept, for athletes and other healthy individuals with a high energy demand, e.g. certain convalescents. However, the demand for improved beverages is still great. **By a healthy individual in the context of this invention**

is intended a human and, as applicable, another mammal individual who is not subject to neither in-patient nor out-patient care for conditions relevant herein by a hospital or a medical or veterinary practitioner. Thus the term excludes patients requiring parenteral, or equivalent enteral, supply of the entire or a very large proportion of the energy, electrolyte, fat or amino acid demand of such patient. On the other hand, the term includes those athletes and convalescents just mentioned and other individuals in a similar physical state, although they may have deficiencies or surplus in their body tissues and liquids as compared to an average non-diseased and fit individual.

(‘364 patent, col. 1, ll. 31 – 54) (emphasis added). Defendants appear to agree that the patentee defined the term “healthy mammal,” but then argue that the later language in the specification regarding this term renders the term indefinite. The Court disagrees.

The specification very clearly provides that by a “healthy individual in the context of this invention” is “intended a human and, as applicable, another mammal individual who is not subject to neither in-patient nor out-patient care for conditions relevant herein by a hospital or a medical or veterinary practitioner.” (‘364 patent, col. 1, ll. 42-46.) The specification then provides additional examples, stating that it *excludes* certain “patients requiring parenteral, or equivalent enteral, supply of the entire or a very large proportion of the energy, electrolyte, fat or amino acid demand of such patient,” and *includes* certain “athletes and convalescents just mentioned and other individuals in a similar physical state.” (*Id.* at col. 1, ll. 47-52.) The specification then states that for a healthy individual, “glutamine is classified as a non-essential nutrient, that is, the body provides enough glutamine to satisfy the metabolic demand for said amino acid. After physical trauma, whether accidental or intentional (e.g. surgery), some non-essential nutrients seem to become semi-essential in order to preserve physical functions such as nitrogen balance and immune function.” (*Id.* at col. 2, ll. 5-11.) The specification then goes on to state that for “the healthy individual, glucose and fatty acids are the predominant energy substrates for the muscle.” (*Id.* at col. 2, ll. 65-66.) The physical tests described in the

specification were administered to “healthy men,” who on a regular basis practiced physical exercise and to “athletes” who were “well trained long distance runners.” (*See, e.g., id.* at col. 6, l. 65 – col. 8, l. 25.) The prosecution history provides additional guidance as to this term, and in one instance, states that “[i]n the healthy individual, glucose and fatty acids are the predominant energy substrates for the muscle.” (*See* Dkt. No. 191-4 (Request for Reconsideration dated October 16, 1997) at 1.)

The Court finds that the term “healthy mammal” is defined in the ‘364 patent. “When a patentee explicitly defines a claim term in the patent specification, the patentee’s definition controls.” *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) (citing *Phillips*, 415 F.3d at 1321). In this instance, the patentee acted as a lexicographer and defined “healthy individual” as the following:

By a healthy individual in the context of this invention is intended a human and, as applicable, another mammal individual who is not subject to neither in-patient nor out-patient care for conditions relevant herein by a hospital or a medical or veterinary practitioner.

(‘364 patent, col. 1, ll. 42 – 46.) While the ‘364 patent provided additional examples of this term and further discussions of a “healthy individual,” these additional discussions do not provide inconsistency to the definition or change the fact that the patentee acted as a lexicographer and that one of ordinary skill would understand the meaning of this term based on the specification.

The Court finds no reason to depart from the construction the patentee provided for this term. At best, the Defendants argue that there is some inconsistency in the specification’s treatment of the term healthy individual and that the use of the word “convalescents” makes the term ambiguous. The Court disagrees. The definition of the term “convalescent” is “a person who is recovering from an illness, an injury, or a surgical operation.” As argued by Plaintiff, the

fact that a person may be recovering from an illness or injury does not mean that the person is subject to inpatient or out-patient care for *conditions relevant* to the claimed invention. The Court agrees with Plaintiff that the specification is clear that a healthy mammal is a mammal whose body is capable of metabolizing energy in a regular way, and the *conditions relevant* to the claimed invention (as stated in the patent’s definition of the term “healthy individual”) are situations related to the metabolism of an individual.

The Court does not find that there are internal inconsistencies to render the claim indefinite. The Court finds that there is no dispute that one of ordinary skill in the art would understand the meaning of the term “healthy mammal” in the context of the claimed invention. Likewise, the Court finds that there is no dispute that one of ordinary skill in the art would understand with “reasonable certainty” the scope of the invention and the bounds of the claims. Accordingly, pursuant to the Supreme Court’s holding in *Nautilus*, the Court rejects Defendants’ arguments that the claim when “read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.”

The Court hereby construes **“healthy mammal”** to mean **“an individual who is not subject to inpatient or outpatient care for metabolic conditions by a hospital or a medical or veterinary practitioner.”**

D. “a beverage, or a dry composition thereof”

| <u>Plaintiff’s</u> <u>Proposed Construction</u> | <u>Defendants’</u> <u>Proposed Construction</u> |
|---|--|
| “beverage, or a powder version of the beverage that can be reconstituted with a liquid” | <u>For beverage:</u> plain and ordinary meaning <u>For a dry composition thereof:</u> “a dry composition for making the claimed beverage” |

The disputed term “a beverage, or a dry composition thereof” appears in claims 1, 2, and 7 of the ‘364 patent.

(1) The Parties’ Positions

Plaintiff submits that the specification of the ‘364 patent indicates that the claimed invention can take the form of “either a beverage or a dry or powder version of the beverage.” (*See, e.g.*, Dkt. No. 191 at 4-5.) Plaintiff argues that because the specification teaches that if the beverage is ready for consumption it comprises water, that either a dry or powder version can be reconstituted with water. (*Id.* at 5.) Plaintiff further argues that Defendants’ construction is ambiguous and does not fully describe the claimed invention as compared to Plaintiff’s more precise construction. (*Id.*)

Defendants respond that the phrase “dry composition therefore” is repeated throughout the specification, does not need a separate construction, and is simply referring back to the previously cited beverage. (*See, e.g.*, Dkt. No. 195 at 24.) Defendants argue that there is no reason to complicate the claim language by adding Plaintiff’s construction, and none of the terms “powder,” “version,” or “reconstituted” appear in the ‘364 patent. (*Id.*) Further, there is nothing in the ‘364 patent that suggests the “dry composition” has to be a “powder.” (*Id.*) Defendants argue that Plaintiff provides no support that Defendants’ construction is improper. (*Id.*)

Plaintiff replies that Defendants' construction is of no use to a jury and is self-defining and provides no context. (*See, e.g.*, Dkt. No. 197 at 9.)

(2) Analysis

The parties dispute whether “beverage” should be separately construed or be included in the larger phrase of “a beverage, or a dry composition thereof.” Because neither party disputes that “beverage” should be given its plain and ordinary meaning, no separate construction is needed and the Court will consider “beverage” as part of the larger phrase of “a beverage, or a dry composition thereof.”

The parties' dispute largely rests on whether a dry composition is just that – a dry composition – or whether it is a powder version. The claim language does not use the term “powder.” Likewise, neither the specification nor any other intrinsic evidence uses the term “powder.” In contrast, the term “dry composition” is used repeatedly in the specification. (*See, e.g.*, '364 patent, col. 3, ll. 49-50, ll. 59-60, ll. 66-67.) Further, the patent specifically mentions that the water-soluble carrier “is in dry form if the beverage is provided as an extract for dilution” and that “[i]f the beverage is provided ready for consumption it further comprises water.” (*Id.* at col. 4, ll. 13-18.)

The Court is not convinced that the broadly used “dry composition” term should be limited to a “powder version.” First, there is no intrinsic support for this “powder” term. Second, it is unclear what the differences (if any) are between a “powder version” and “dry composition.” Third, even if the terms had the same or similar meanings, there is no reason to substitute the term “powder” for the disputed term as the Court is not convinced that simply replacing easily understood terms with other terms is either helpful to the jury or appropriate. Because construing the “dry composition” term will only tend to confuse rather than clarify, the

term requires no further construction. *See U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (“Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy.”); *see also O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) (“[D]istrict courts are not (and should not be) required to construe every limitation present in a patent’s asserted claims.”) (*citing U.S. Surgical*, 103 F.3d at 1568). The Court finds that the term “dry composition” has no special meaning other than its plain and ordinary meaning. The Court agrees with the Defendants that the term “thereof” is simply referring back to the claimed beverage. Further, during the claim construction hearing Plaintiff withdrew its request to limit the phrase “dry composition” to a “powder version of the beverage.”

The Court hereby construes “**a beverage, or a dry composition thereof**” to mean “**a beverage, or a dry composition for making the beverage.**”

E. “comprising 0.1 to 2.5 percent of the wet weight of α -ketoglutaric acid”

| <u>Plaintiff’s Proposed Construction</u> | <u>Defendants’ Proposed Construction</u> |
|---|--|
| “includes 0.1 to 2.5 grams of alpha-ketoglutaric acid per 100 ml of liquid” | Plain and ordinary meaning |

The disputed term “comprising 0.1 to 2.5 percent of the wet weight of α -ketoglutaric acid” appears in claims 1 and 7 of the ‘364 patent.

(1) The Parties’ Positions

Plaintiff submits that the disputed phrase needs a precise definition for clarity. (*See, e.g.*, Dkt. No. 191 at 8.) Plaintiff argues that its construction is supported by the specification’s use of

a certain amount of grams of alpha-ketoglutaric acid per 100 ml of liquid for various preferred beverages. (*Id.*) The Plaintiff also argues that the prosecution history confirms its construction. (*Id.* at 8-9.)

Defendants respond that the phrase is understandable and does not need construction. (Dkt. No. 195 at 25.) Defendants argue that, read in context, the phrase is referring to the weight of alpha-ketoglutaric acid as a percentage of the overall weight of the beverage. (*Id.*) Defendants argue that Plaintiff's construction impermissibly changes the scope of the claim term. (*Id.*) Plaintiff's construction does not specify what the liquid is, and because different liquids have different densities, using a fixed amount of alpha-ketoglutaric acid in one liquid may provide a different wet weight percentage as opposed to another liquid. (*Id.*) While the specification provides an example of using 0.5 to 2.0 grams of alpha-ketoglutaric acid per 100 ml, the specification is silent as to how much of that 100 ml is water, whether other ingredients are liquid, and what the wet range of the beverage is. (*Id.*) For example, Defendants argue that a 100ml beverage made according to Example 1 is actually 105.3 grams. (*Id.* at 26.) Defendants also argue that the prosecution history cited by Plaintiff does not trump (and is not found in) the claim language and specification and is a misreading of the relevant specification results. (*Id.*)

Plaintiff replies that its construction explains the calculation required to determine the wet weight of the claimed invention. (Dkt. No. 197 at 9.) Plaintiff's construction is consistent with the examples of preferred beverages disclosed in the '364 patent and the tests disclosed in the patent. (*Id.*)

(2) Analysis

There is no dispute between the parties that the claims clearly recite "comprising 0.1 to 2.5 percent of the wet weight of α -ketoglutaric acid." The terms "wet" and "wet weight" are not

used in the specification of the '364 patent. The dispute between the parties is whether the phrase should mean what it clearly states (as proposed by Defendants) or whether it should be limited to the embodiment provided in the specification (as proposed by Plaintiff).

In one part of the patent, two particularly preferred beverages are described: one beverage has a preferred range of 0.5-2.0 g of alpha-ketoglutaric acid per 100 ml and another beverage has a preferred range of 1.0-1.5 g of alpha-ketoglutaric acid per 100 ml. (*See, e.g.*, col. 4, ll. 35-60.) Two other examples in the '364 patent specifically provide 1.2 and 1.5 grams of alpha-ketoglutaric acid per 100 ml. (*Id.* at col. 6, ll. 5-30.) For Physical Test 2 a beverage was provided with varying content of 0.01 and 3.5 grams of alpha-ketoglutaric acid per 100 ml. (*Id.* at col. 7, ll. 44-47.) The '364 patent teaches that individuals reported enhanced performance when consuming a beverage of between 0.1 and 2.5 g of alpha-ketoglutaric acid per 100 ml. (*Id.* at col. 7, ll. 53-56.)

Plaintiff argues that the prosecution history supports its construction. In a Request for Reconsideration dated October 16, 1997, the Applicant characterized its invention and argued around various prior art references. (*See* Dkt. No. 191-4 (Request for Reconsideration).) The Applicant made various citations to the prior art as not having a certain percentage by weight of a particular component. (*See id.* at 4-5.) In one instance, the Applicant cited to the specification of the pending application and argued “a beverage containing 0.1 g of α -ketoglutaric acid per 100 ml (0.1% by weight) was deemed effective.” (*Id.* at 5.) Thus, Plaintiff argues that the Applicant equates the phrase “percent of wet weight” to grams per 100 ml.

On balance, the Court finds that the claim language controls and rejects Plaintiff's construction. While there is some support for Plaintiff's construction in the intrinsic record, neither the specification nor the prosecution history uses the term “wet” or “wet weight” and

there is nothing in the intrinsic record that necessitates Plaintiff's construction. The Federal Circuit has consistently held that "particular embodiments appearing in the written description will not be used to limit claim language that has broader effect." *Innova/Pure Water*, 381 F.3d at 1117. Further, the prosecution history cited by Plaintiff does not persuade the Court that the plain meaning of the claim term should be changed. There is no dispute that the disputed term is easily understandable or that one of ordinary skill would understand what the term means. Had the Applicant intended to mean a certain amount of grams per 100 ml of liquid – as Plaintiff argues – it could have easily claimed such a limitation. In contrast, it specifically used the "comprising 0.1 to 2.5 percent of the wet weight of α -ketoglutaric acid" language. Absent clear evidence to the contrary, the Court is hesitant to change the plain meaning of a term. Because a plain and ordinary meaning construction resolves the dispute between the parties as to this term, no further construction is necessary. *See U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."); *see also O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("[D]istrict courts are not (and should not be) required to construe every limitation present in a patent's asserted claims.") (*citing U.S. Surgical*, 103 F.3d at 1568).

The Court hereby construes "**comprising 0.1 to 2.5 percent of the wet weight of α -ketoglutaric acid**" to have its plain meaning.

F. “water-soluble innocuous salt thereof”

| <u>Plaintiff’s</u> <u>Proposed Construction</u> | <u>Defendants’</u> <u>Proposed Construction</u> |
|--|--|
| “a water-soluble salt of alpha-ketoglutaric acid that is harmless and does not have an objectionable taste or other negative characteristic or does not otherwise interfere with the intended use of the beverage” | “A salt that would not harm the subject and where the non- α -ketoglutaric acid portion of the salt is not a physiologically active compound” |

The disputed term “water-soluble innocuous salt thereof” appears in claims 1 and 7 of the ‘364 patent.

(1) The Parties’ Positions

Plaintiff submits that the specification and prosecution history support its proposed construction. (*See, e.g.*, Dkt. No. 191 at 9-10.) In particular, the Plaintiff argues that the USPTO, in its rejection of the inter partes petition of the ‘364 patent, found that the term “innocuous salt thereof” encompasses innocuous salts of alpha-ketoglutarate. (*Id.*) Plaintiff also relies on various prior art references and dictionary definitions. (*Id.* at 10.) Plaintiff argues that innocuous does not mean inactive and there is no reason to believe that the non-alpha-ketoglutaric acid portion of the salt is not a physiologically active compound. (*Id.*)

Defendants respond that Plaintiff’s construction captures products with complex, physiologically active amino acids in combination with α -ketoglutarate by calling such combinations “innocuous salts.” (*See, e.g.*, Dkt. No. 195 at 15.) Defendants’ construction seeks to exclude those complex compounds from being “innocuous salts.” (*Id.*) Defendants argue that their construction is based in the prosecution history, the claim language, the specification, the relevant science of metabolism, the USPTO’s claim construction during the inter partes review decision, and common sense. (*Id.* at 16-23.)

Plaintiff replies that Defendants' construction is unsupported by the patent specification, the prosecution history, and the meaning of the term "complex" in terms of the prior art. (*See, e.g.*, Dkt. No. 197 at 7-9.) Plaintiff argues that there is no reason that an innocuous salt component must be limited to a simple inert or inactive component. (*Id.* at 7.)

(2) Analysis

The intrinsic record is clear that claims 1 and 7 include water-soluble innocuous salts that can be substituted for the alpha-ketoglutaric acid. The parties' primary dispute as to this term is whether innocuous means inactive (as argued by Defendants) or whether it means harmless and without any negative consequences (as argued by Plaintiff). In particular, the parties dispute whether the salt can include complex, physiologically active amino acids in combination with alpha-ketoglutarate. The Defendants provide multiple arguments as to why the equivalent salt must be inactive. Defendant's substantive arguments are addressed below.

The claim language and specification are not that helpful as to this dispute. Nothing in the specification or claim language provides any specific guidance as to what is meant by a salt or by the term "innocuous." Nonetheless, there seems to be no dispute that alpha-ketoglutarate is simply the anion form of alpha-ketoglutaric acid, that alpha-ketoglutarate is formed by removing the hydrogen atoms from α -ketoglutaric acid, and that a salt of alpha-ketoglutaric acid is then formed by replacing the removed hydrogen atoms with another substance. However, the '364 patent disclosure provides no guidance as to whether the innocuous salt may include an active portion separate from the alpha-ketoglutaric acid component. Defendants argue that the Applicant would not have included complex, physiologically active amino acids in combination with α -ketoglutarate within the claims' scope without disclosing them or doing testing on them. (*See, e.g.*, Dkt. No. 195 at 17.) Defendants argue that if the claims at issue extend to cover

physiologically active amino acids in combination with α -ketoglutarate, the patent may well be invalid to due lack of enablement/utility. (*Id.*) The Court does not find Defendants' arguments persuasive here. The mere fact that the specification does not teach all salt variations does not necessarily preclude a broad claim from covering multiple salt embodiments. Further, the Court finds that these are largely written description or enablement arguments and not necessarily claim construction arguments. Whether or not the specification sufficiently enables or describes a particular claim term is a validity argument – not a claim construction argument – and the Court will not address these separate issues at this time.

Defendants also argue that the relevant science contradicts Plaintiff's construction. (*See, e.g.,* Dkt. No. 195 at 18.) Defendants argue that complex, physiologically active amino acids in combination with α -ketoglutarate behave differently in the human body than do simple mineral salts of α -ketoglutaric acid or α -ketoglutaric acid alone. (*Id.*) Because ornithine, arginine, and glutamine alpha-ketoglutarate would have different effects on the human body from alpha-ketoglutaric acid alone, Defendants argue that it is unlikely that one skilled in the art would consider such physiologically active amino acids in combination with alpha-ketoglutarate "innocuous." (*Id.* at 19.) Instead, a salt of alpha-ketoglutaric acid is formed by replacing removed hydrogen atoms from the acid with another substance, such as sodium (relied upon by the PTAB). (*Id.* at 20.) The Court finds that these arguments are not determinative as to the meaning of "innocuous." Whether a complex, physiologically active amino acid in combination with α -ketoglutarate acts differently than a mineral salt of alpha-ketoglutaric acid does not necessarily preclude such a compound from being considered as an "innocuous" salt.

Defendants also provide a "common sense" argument, in that if Plaintiff's construction were correct, then almost any combination with or salt of alpha-ketoglutaric acid would be

included within the scope of the asserted claims and would effectively read the term “innocuous” out of the claims. (*Id.* at 21.) The Court finds that these arguments are not determinative as to the meaning of “innocuous.” A common meaning for the term “innocuous” is harmless. The fact that a wide variety of salts could be considered “harmless” does not render this limitation superfluous.

Defendants rely mostly on the prosecution history in support of their arguments. First, Defendants argue that the Applicant disclaimed physiologically active amino acids in combination with alpha-ketoglutarate during the original prosecution of the ‘364 patent in the context of treating trauma or surgery patients. (*See, e.g.*, Dkt. No. 195 at 16.) As to this argument, the Court does not find any evidence of disclaimer – particularly any “clear” and “unambiguous” disclaimer – that the salts must be inactive salts and not physiologically active amino acids. Second, Defendants argue that the PTAB opinion supports their construction. (*See, e.g.*, Dkt. No. 195 at 20-21.) In front of the PTAB were various prior art references that included both complex and inactive salts. These include a monosodium salt of alpha-ketoglutarate (the Kihlberg reference) and a complex salt of alpha-ketoglutarate pyridoxine (the Marconi reference and the Glutarase Catalog reference), which is an alpha-ketoglutarate with vitamin B6 (pyridoxine). (*See, e.g.*, Exh. 191-5 at 921-989.) For the Marconi reference, which was directed to a complex of alpha-ketoglutarate with pyridoxine, the Applicant repeatedly stated that the Marconi reference did not teach that alpha-ketoglutaric acid could be used alone and only that when it was combined with the pyridoxine it was useful for enhancing energy. (*See, e.g.*, Patent Owner’s Preliminary Response to Petition, dated August 23, 2013, Dkt. No. 191-5 at 979.) The Applicant described pyridoxine as a physiologically active molecule also known as vitamin B6. (*Id.* at 981). The Applicant further distinguished the Marconi reference as being directed not to

“particular amounts of AKG [alpha-ketoglutaric acid]” but to the “administration of a complex between AKG and another physiologically active substance, pyridoxine” and that it taught that AKG alone was not useful in situations that require a rapid energy supply. (*Id.* at 982-83.) The PTAB Opinion agreed with the Applicant and stated that the Marconi reference did not teach that alpha-ketoglutarate had the same effect as the alpha-ketoglutarate pyridoxine complex, which “has properties that are distinct from its individual components.” (PTAB Opinion at 8, Dkt. No. 191-5 at 997.) Further, the PTAB Opinion stated “an ordinary artisan would understand that a water-soluble innocuous salt of alpha-ketoglutaric acid is alpha-ketoglutarate, wherein the hydrogen atoms of the alpha-ketoglutaric acid are substituted with an anion [sic], such as a sodium anion.” (*Id.* at 995.)

Based on the prosecution history as a whole, the Court finds that Plaintiff distinguished the Marconi reference from its claimed invention and the PTAB relied on this distinction. The Court finds that the primary reason that the Applicant obtained its claims was that the prior art did not teach that alpha-ketoglutaric acid (or an innocuous salt thereof) *by itself* provided the desired energy supply. The Court must give affect to the prosecution history. *See Phillips*, 415 F.3d at 1317. Accordingly, consistent with the express language used by the Applicant during the inter partes petition, the Court finds that the claimed invention cannot apply to the type of structure disclosed in Marconi – the “administration of a complex between AKG and another physiologically active substance.”

Both parties agree that “innocuous” means “harmless.” The Court rejects Plaintiff’s proposal that the term also means that it “does not have an objectionable taste or other negative characteristic or does not otherwise interfere with the intended use of the beverage.” Such a

construction has no support in the specification and the Court is not convinced that it is necessary.

The Court hereby construes “**water-soluble innocuous salt thereof**” to mean “**a harmless, water-soluble salt of alpha-ketoglutaric acid that is not a complex between alpha-ketoglutaric acid and another physiologically active substance.**”

G. “wherein α -ketoglutaric acid is combined with malic acid”

| <u>Term</u> | <u>Plaintiff’s Proposed Construction</u> | <u>Defendants’ Proposed Construction</u> |
|--|--|--|
| “wherein α -ketoglutaric acid is combined with malic acid” (claim 2) | This should be construed in context. The term “alpha-ketoglutaric acid” means alpha-ketoglutaric acid or its water-soluble innocuous salt. The term “malic acid” means malic acid or its equivalent salt when in dry form. | Limited to formulations using α -ketoglutaric acid only, and excluding formulations using a salt of the acid or the α -ketoglutarate anion combined with formulations using malic acid only, and excluding any salt of malic acid. |
| “malic acid” (claim 2) | “malic acid or its equivalent salt when in dry form” | Limited to formulations using malic acid only, and excluding formulations using any salt of malic acid. |
| “ α -ketoglutaric acid” (claim 2) | This term should be construed in context, and means alpha-ketoglutaric acid or its water-soluble innocuous salt. | Limited to formulations using α -ketoglutaric acid only, and excluding formulations using a salt of the acid or the α -ketoglutarate anion. |

The disputed term “wherein α -ketoglutaric acid is combined with malic acid” appears in claim 2 of the ‘364 patent. The parties also dispute separately the constituent terms of “ α -ketoglutaric acid” and “malic acid.”

(1) The Parties’ Positions

Plaintiff submits that, in the context of the patent, the term “alpha-ketoglutaric acid” means “alpha-ketoglutaric acid or its water-soluble innocuous salt” and the term “malic acid” means “malic acid or its equivalent salt when in dry form.” (*See, e.g.*, Dkt. No. 191 at 11, 17, 18,

21.) Plaintiff argues that because claim 2 recites a “beverage, or a dry composition therefor,” that claim 2 necessarily encompasses a dry form of the claimed invention and thus the recited alpha-ketoglutaric acid and malic acid would include the equivalent salts. (*Id.* at 11, 17.) Plaintiff argues that one of ordinary skill in the art would understand that the ‘364 patent teaches the use of equivalent salts and that salts are readily interchangeable with the acids. (*Id.*) Plaintiff argues that Defendants’ construction imposes a limitation not supported by the patent specification or the understanding of a person having ordinary skill in the art. (*Id.* at 21.)

Defendants respond that claim 2 cannot be construed to include salts of each acid because such a construction substantially alters what the ‘364 patent claims and would render limitations from both independent claims superfluous and redundant. (*See, e.g.*, Dkt. No. 195 at 27.) Defendants argue that the specification and claims repeatedly distinguishes between acids and salt. (*Id.*) Defendants also argue that the Federal Circuit opinion in *Pfizer v. Ranbaxy Labs.* supports their construction and that the PTAB Opinion also supports their construction. (*Id.* at 28-29.)

Plaintiff replies that Defendants’ constructions are not supported by the patent. (*See, e.g.*, Dkt. No. 197 at 9-10.) Plaintiff argues that limiting the construction of the claim to malic acid alone and not the salt of malic acid is to ignore the language of the claim itself. (*Id.* at 10.) Plaintiff argues that because claim 2 claims a “beverage, or a dry composition therefor,” the dry form of the invention in claim 2 would necessarily include the equivalent salts of malic acid and alpha-ketoglutaric acid. (*Id.*)

(2) Analysis

The parties’ primary dispute is whether the acids recited in claim 2 should be interpreted to include their innocuous salts despite the claim not expressly including any salts. While the

parties dispute and brief each of the “malic acid” and “alpha-ketoglutaric acid” terms separately, the Court considers these terms in the larger phrase of “wherein α -ketoglutaric acid is combined with malic acid” and no separate constructions for the constituent terms are necessary.

Claim 1 of the ‘364 patent expressly states the use of “alpha-ketoglutaric acid” or its “water soluble innocuous salt”:

1. A beverage, or a dry composition therefor, providing an energy source in situations with demand of large and rapid energy supply to a healthy mammal comprising 0.1 to 2.5 percent of the wet weight of **α -ketoglutaric acid or a water-soluble innocuous salt thereof** together with a nutritionally acceptable water-soluble carrier.

(Emphasis added.) Thus, by its simple claim language, claim 1 treats and claims “alpha-ketoglutaric acid” different than its “water soluble innocuous salt.” In contrast, claim 2 expressly recites only acid components and not salts:

2. A beverage, or a dry composition therefor, according to claim 1, **wherein α -ketoglutaric acid is combined with malic acid.**

(Emphasis added.)

Plaintiff relies on primarily two arguments for its proposed construction. First, because claim 2 recites a “beverage, or a dry composition therefor,” the mere recitation of the acids would also by necessity include the equivalent salts. Second, one of ordinary skill in the art would understand the patent to teach the use of equivalent salts for malic acid and alpha-ketoglutaric acid and thus the claims should not exclude such salts. The Court does not find either argument persuasive. First, the mere reference back to the preamble of claim 1 does not trump the clear recitation of only “malic acid” and “alpha-ketoglutaric acid.” Second, the fact – even if true – that one of ordinary skill in the art would understand that equivalent salts could be substituted for acids to obtain the benefits recited in the invention does not trump or account for

the lack of the term “salt” in the claim language. Further, there is no disclosure in the ‘364 patent of using equivalent salts in place of malic acid.

The Court finds that, based on the express claim language, the mere recitation of “alpha-ketoglutaric acid” and “malic acid” does not include any equivalent salts. It is clear that the Applicant knew how to claim an innocuous salt of an acid when desired (as the Applicant did in claim 1). The fact that the Applicant did not do so in claim 2 and did so in claim 1 provides strong support that the mere recitation of acids in claim 2 does not also include their innocuous salts. *See also Pfizer, Inc. v Ranbaxy Laboratories Ltd.*, 457 F.3d 1284, 1291-92, n. 6 (Fed. Cir. 2006) (when a dependent claim only recited an acid and did not include the language “pharmaceutically acceptable salts thereof” found in the independent claim, the dependent claim did not include any corresponding salts). If one of ordinary skill in the art would understand that the recitation of acids necessarily includes their equivalent salts (as proposed by Plaintiff), then there would be no need for the recitation of such “innocuous salts” in claim 1. Further, there is no reference or teaching in the ‘364 patent that innocuous salts of malic acid can be used. Still further, this construction is consistent with the PTAB Opinion, in which the PTAB declined to find that the simple recitation of “alpha-ketoglutaric acid” would necessarily include the alpha-ketoglutaric acid and its anion, the alpha-ketoglutarate salt. (PTAB Opinion at 6.)

Absent clear evidence to the contrary, the Court is hesitant to change the plain meaning of a term. Because a plain and ordinary meaning construction – one that is limited to the recited acids and not the inclusion of their salts – resolves the dispute between the parties as to this term, no further construction is necessary. *See U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (“Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the

claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy.”); *see also O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) (“[D]istrict courts are not (and should not be) required to construe every limitation present in a patent’s asserted claims.”) (*citing U.S. Surgical*, 103 F.3d at 1568).

The Court hereby construes “**wherein α -ketoglutaric acid is combined with malic acid**” to have its plain meaning. Separate constructions of the constituent terms are not necessary.

IV. CONCLUSION

The Court adopts the above constructions set forth in this opinion for the disputed terms of the patent-in-suit. The parties are ordered that they may not refer, directly or indirectly, to each other’s claim construction positions in the presence of the jury. Likewise, the parties are ordered to refrain from mentioning any portion of this opinion, other than the actual definitions adopted by the Court, in the presence of the jury. Any reference to claim construction proceedings is limited to informing the jury of the definitions adopted by the Court.

SIGNED this 3rd day of November, 2014.


ROY S. PAYNE
UNITED STATES MAGISTRATE JUDGE