

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

KEMIN FOODS, L.C., and CATHOLIC
UNIVERSITY OF AMERICA,

Plaintiffs,

v.

Case No. 8:07-cv-1308-T-33TGW

OMNIACTIVE HEALTH TECHNOLOGIES,
INC., and OMNIACTIVE HEALTH
TECHNOLOGIES PRIVATE, LTD.,

Defendants.

ORDER

This cause is before the Court pursuant to OmniActive Health Technologies, Inc.'s Motion for Summary Judgment of Noninfringement (Doc. # 103), which was filed on September 24, 2008.¹ Plaintiffs responded to the motion for summary judgment on January 16, 2009 (Doc. # 162), and Defendants filed a reply (Doc. # 188) on February 27, 2009. In addition, both sides have filed numerous claim construction briefs. (Doc. # 158, 161, 179, 181). Thereafter, on August 20, 2009, the parties filed a joint claim construction stipulation. (Doc. # 244).

¹ This Court referred the motion for summary judgement to the Magistrate Judge for the issuance of a Report and Recommendation on September 30, 2008. (Doc. # 109). The Court entered an order withdrawing the referral on May 22, 2009. (Doc. # 205).

The Court held a Markman hearing and oral argument on the motion for summary judgment on August 25, 2009. (Doc. # 250). Plaintiffs and Defendants filed supplemental briefs regarding claim construction and summary judgment on August 14, 2009. (Doc. # 238, 239).

I. Background

Plaintiff Kemin Foods, L.C., is an Iowa limited liability company that develops purified lutein for human consumption. (Doc. # 83 at ¶ 10). Kemin's purified lutein is made using a patented process. Specifically, on January 17, 1995, United States Patent No. 5,382,714 (the "'714 patent"), titled "Process for Isolation, Purification and Recrystallization of Lutein from Saponified Marigold Oleoresin and Uses Thereof" was legally issued to inventor Frederick Khachik, Ph.D. (Id. at ¶ 14). Plaintiff Catholic University of America is the owner, through assignment, of the '714 patent, and Plaintiff Kemin is the exclusive licensee of the '714 patent. (Id. at ¶ 15).

OmniActive Health Technologies Private, Ltd. (hereafter "OmniActive India") and OmniActive Health Technologies, Inc. (hereafter "OmniActive USA") are the maker and distributor, respectively, of "Lutemax" and "Lutemax Free Lutein," lutein products that compete with Plaintiffs' lutein products.

Plaintiffs learned that Defendants supplied lutein products to Medical Ophthalmics in the Middle District of Florida (particularly, Oldsmar), and believe that Defendants' "Lutemax" products infringe the '714 patent. (Doc. # 83 at ¶ 11). Furthermore, Plaintiffs allege that Defendants falsely advertised and falsely marked certain products under a different patent: U.S. Patent No. 6,743,953. (Id. at ¶ 12). Last, Plaintiffs argue that Defendants made false and misleading claims in advertisements, marketing materials, and communications with customers about Kemin's products.

On July 25, 2007, Plaintiffs filed suit against OmniActive USA. (Doc. # 1). Plaintiffs thereafter filed an amended complaint against both OmniActive USA and OmniActive India alleging patent infringement of the '714 patent (count one), false marking (count two), false advertising (count three), violation of Florida Statute Section 817.41, which criminalizes false advertising (count four), violation of Florida Statute Section 501.201, the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA")(count five), violation of Florida Common Law of Unfair Competition (count six), and product disparagement (count seven). (Doc. # 83).

On August 13, 2009, OmniActive India filed its answer, affirmative defenses, and counterclaims against Plaintiffs.

(Doc. # 236). OmniActive India's counterclaims against Plaintiffs include declaratory judgment of noninfringement and patent invalidity (counterclaim one), declaratory judgment of patent unenforceability (counterclaim two), unfair competition (counterclaims three and four), violation of FDUTPA (counterclaim five), and false patent marking (counterclaim six). (Doc. # 236).

II. Summary Judgment Proceedings

OmniActive USA filed the motion for summary judgment (Doc. # 103) on September 24, 2008, arguing that "Plaintiffs cannot prove, and no reasonable jury could conclude, that the accused product, Lutemax Oil Suspension, contains all elements of any asserted patent claim." (Doc. # 103 at 1).

The motion for summary judgment is ripe for the Court's review. However, as discussed below, the Court must construe the claims in the '714 patent before it can address the issues raised in the motion for summary judgment.

III. Legal Standard

A. Literal Infringement and the Doctrine of Equivalents

"To establish infringement of a patent, every limitation set forth in a claim must be found in an accused product or

process exactly or by a substantial equivalent." Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 796 (Fed. Cir. 1990)(citation omitted). In adjudging patent infringement cases, the Court performs two steps: "First, a court must determine as a matter of law the correct scope and meaning of a disputed claim term." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1365 (Fed. Cir. 2002). Second, the Court compares "the properly construed claims to the accused device, to see whether that device contains all the limitations, either literally or by equivalents, in the claimed invention." Id.

Literal infringement requires that the accused device contain each and every limitation of a claim. Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc., 389 F.3d 1370, 1378 (Fed. Cir. 2004). The doctrine of equivalents, on the other hand, "prevents competitors from pirating the essence of an invention while narrowly avoiding the literal language of the claims." H2Ocean, Inc. v. Schmitt, No. 3:05cv387/RV/EMT, 2007 U.S. Dist. LEXIS 59720, *3 (N.D. Fla. Aug. 15, 2007). The doctrine of equivalents "is intended to prevent a competitor from making merely insubstantial changes to the patented product and passing it off as a new product." Id.

The doctrine of equivalents applies if each limitation of the claim is equivalently present in the accused device. Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc., 206 F.3d 1408, 1415 (Fed. Cir. 2000) (citations omitted). "Equivalently present" means "there must be only 'insubstantial differences' between the missing claim limitation and corresponding aspects of the accused device." Id.

B. Claim Construction

Construing claims, including a claim's terms of art, is within the court's exclusive province. Markman v. Westview Instruments, Inc., 517 U.S. 370, 376 (1996). "Claim construction begins with an examination of the 'intrinsic evidence': the claims themselves; the patent specification, which includes the remainder of the written and graphic description of the invention in the patent; and the patent prosecution history, which includes the patent application and correspondence between a patentee and the Patent and Trademark Office examiners reviewing the application." Guardian Pool Fence Sys., Inc. v. Baby Guard, Inc., 228 F.Supp.2d 1347, 1353 (S.D. Fla. 2002) (citation omitted). Extrinsic evidence, such as expert testimony or treatises, may also be considered in determining the scope and meaning of a claim term. Id.

No formal claim construction hearing is required at the

summary judgment stage if the issues on which the summary judgment motion turns can be otherwise resolved. See H2Ocean, at *3. The Federal Circuit holds:

Markman does not require a district court to follow any particular procedure in conducting claim construction. It merely holds that claim construction is the province of the court, not a jury. . . . If the district court considers one issue to be dispositive, the court may cut to the heart of the matter and need not exhaustively discuss all the other issues presented by the parties. District courts have wide latitude in how they conduct the proceedings before them, and there is nothing unique about claim construction that requires the court to proceed according to any particular protocol. As long as the trial court construes the claims to the extent necessary to determine whether the accused device infringes, the court may approach the task in any way that it deems best.

Ballard Med. Prods. v. Allegiance Healthcare Corp., 268 F.3d 1352, 1358 (Fed. Cir. 2001).

Although an infringement analysis typically begins with claim construction, "the sequence of this process is not absolute, and, in an effort to avoid advisory opinions, only terms that are disputed, thereby placing such terms actually in controversy in the infringement litigation, are construed."

Mextel, Inc. v. Air-Shields, Inc., No. Civ. A. 01-CV-7308, 2005 U.S. Dist. LEXIS 1281, *142 (E.D. Pa. Jan. 31, 2005) (citing Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341, 1350 (Fed. Cir. 2004)).

"Furthermore, the lack of an express claim construction by the Court does not absolve plaintiffs of their burden at the summary judgment stage to provide factual support for the conclusion that each and every limitation in the germane claims of the . . . patent[] reads on the accused device[]." Mextel, at *143 (citing Linear Tech. Corp. v. Impala Linear Corp., 379 F.3d 1311, 1325 (Fed. Cir. 2004)).

C. Summary Judgment

The Federal Circuit set forth the standard for evaluating summary judgment in patent cases in Novartis Corp. v. Ben Venue Labs., Inc., 271 F.3d 1043, 1046 (Fed. Cir. 2001): "Summary judgment is appropriate when, after opportunity for discovery and upon motion, there is no genuine dispute of material fact for trial and one party is entitled to judgment as a matter of law." Id. "Summary judgment must be granted against a party who has failed to introduce evidence sufficient to establish the existence of an essential element of that party's case, on which the party will bear the burden of proof at trial." Id.

"Summary judgment is appropriate when it is apparent that only one conclusion as to infringement could be reached by a reasonable jury." Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1323 (Fed. Cir. 2001). Further, "summary

judgment of noninfringement is appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, since such failure will render all other facts immaterial." Id.

The summary judgment movant has the initial responsibility of identifying the legal basis of its motion and of pointing to those portions of the record that it believes demonstrate the absence of a genuine issue of material fact. Celotex Corp v. Catrett, 477 U.S. 317, 323 (1986). Once the movant has made this showing, the burden shifts to the nonmovant to designate specific facts showing that there is a genuine issue for trial. Id. at 324.

Since the ultimate burden of proving infringement rests with the patentee, an accused infringer seeking summary judgment of noninfringement may meet its initial responsibility either by providing evidence that would preclude a finding of infringement, or by showing that the evidence on file fails to establish a material issue of fact essential to the patentee's case. Vivid Tech, Inc. v. Am. Sci. & Eng'g., Inc., 200 F.3d 795, 807 (Fed. Cir. 1999). "Summary judgment of noninfringement may only be granted if, after viewing the alleged facts in the light most favorable to the nonmovant and drawing all justifiable inferences in the

nonmovant's favor, there is no genuine issue whether the accused device is encompassed by the patent claims." Novartis Corp., 271 F.3d at 1046.

IV. The '714 Patent: Claim Construction

Defendants move for summary judgment of noninfringement of the '714 patent. Plaintiffs accuse Defendants of infringing claims 1, 2, and 4 of the '714 patent.²

Claims 1, 2, and 4 follow:

1. The carotenoid composition consisting essentially of substantially pure lutein crystals derived from plant extracts that contain lutein, said lutein crystals being of the formula: [formula deleted] wherein the lutein is substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract.
2. The lutein carotenoid composition of claim 1 wherein the plant extract is derived from naturally occurring plants selected from the group consisting of fruits, vegetables and marigolds.
4. The lutein carotenoid composition of claim 1 wherein the lutein is derived from marigold flower extract.

The motion for summary judgment cannot be decided until the Court construes claim 1.

A. The PIVEG Litigation

²All of the disputed claim language appears in claim 1 because claim 1 is an independent claim, and claims 2 and 4 are dependent on claim 1. (Doc. # 244 at 1).

The Court must determine the meaning of disputed language in claim 1. Both Plaintiffs and Defendants agree that prior litigation known as the "PIVEG" litigation is relevant to, but not completely dispositive of, the parties' dispute.

Kemin initiated the PIVEG litigation on July 9, 2002, when it filed a complaint against Pigmentos Vegetales Del Centro, S.A. ("PIVEG"), a Mexican manufacturer of purified lutein, alleging, among other things, patent infringement of claims 1, 2, and 4 of the '714 patent. Kemin also moved for a preliminary injunction against PIVEG, which the district court granted on January 2, 2003. Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro, S.A., 240 F.Supp.2d 963, 982 (S.D. Iowa 2003).

Thereafter, the district court held a Markman hearing and issued its initial claim construction order on January 13, 2004, construing claim 1 as follows:

One of ordinary skill in the art would understand the plain meaning of claim 1 of the '714 patent to provide for a carotenoid composition consisting essentially of substantially pure lutein crystals, where 'substantially pure' refers to the lutein purity as compared to the carotenoid composition and requiring purity that is 90% or greater, as measured by UV/visible spectrophotometry in conjunction with HPLC, and/or otherwise suitable for human consumption.

Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro, S.A., 301

F.Supp.2d 970, 988-89 (S.D. Iowa 2004).

In March 2004, the Federal Circuit reversed the district court's grant of a preliminary injunction. Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro, S.A., 93 F. App'x 225 (Fed. Cir. Mar. 17, 2004). In the order reversing the preliminary injunction, the Federal Circuit commented on the district court's claim construction. Specifically, the Federal Circuit determined that it was "error for the [district] court to have read the limitation 'suitable for human consumption' into the claims, either as an alternative to the 90% minimum or in conjunction with it." Id. at 232. Further, the Federal Circuit found that the claimed composition must contain "no traces of toxic chemicals." Id.

On May 18, 2004, the district court amended its claim construction so that it would comport with the Federal Circuit's specifications. Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro, S.A., 319 F.Supp.2d 939, 943 (S.D. Iowa 2004). Thereafter, on February 8, 2005, the district court issued its final claim construction, which follows:

The composition covered in claim 1 consists of lutein greater than about 90% pure, having significantly less than 10% of other carotenoids, and no traces of toxic chemicals. Lutein purity is to be measured as related to the carotenoid composition and is determined by UV/visible spectrophotometry in conjunction with HPLC.

357 F.Supp.2d 1105, 1122 (S.D. Iowa 2005), aff'd in relevant part, 464 F.3d 1339 (Fed. Cir. 2006). Notably absent from the final claim construction is any discussion of what is "suitable for human consumption."

After a trial, a jury determined that claims 1, 2, and 4 of the '714 patent were valid, but that PIVEG did not infringe the patent either literally or under the doctrine of equivalents. Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro, S.A., 357 F.Supp.2d 1105, 1122-24 (S.D. Iowa 2005). On appeal, the Federal Circuit upheld the verdict of noninfringement. Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro, S.A., 464 F.3d at 1349. The Federal Circuit did not alter the district court's final claim construction.

The Court accepts the district court's final claim construction in the PIVEG litigation as enumerated above; however, the Court cannot rest on such construction because the parties disagree about the meaning of the following terms: "lutein;" "substantially pure;" "substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract;" and "no traces of toxic chemicals."³

³ The terms "lutein;" "substantially pure;" and "substantially free from other carotenoids and chemical

1. "Lutein"

The parties disagree as to what "Lutein" means for the purposes of measuring lutein purity. Plaintiffs contend that "Lutein" includes all isomers of lutein. As explained by Plaintiffs, "Lutein is lutein." (Doc. # 161 at 15). Defendants, on the other hand, assert that "Lutein" means only "trans-lutein" also known as "e-lutein." In support of this proposition, Defendants note that the inventor defines "lutein" as "trans-lutein" or "e-lutein."

While the '714 patent states at one point, "Unless specified lutein refers to all -E (all-trans) isomer" ('714 patent, Column 1, Lines 40-41), the patent later uses the term "lutein" to refer to all isomers of lutein. ('714 patent, Column 6, Lines 44-45; Column 7, Lines 26-42).⁴

Furthermore, the Court realizes that the language of claim 1 uses a depiction of a lutein isomer that happens to be trans-lutein. However, all isomers of lutein bear the same formula. As explained in the report of Steven J. Schwartz,

impurities found in the natural form of lutein in the plant extract;" are terms in claim 1. The term "no traces of toxic chemicals" is a term that evolved from the construction of claim 1 in the PIVEG litigation.

⁴ The '714 patent has been filed with the Court and is located at Doc. # 163-2.

Ph.D., "The '714 patent refers to a formula for lutein that includes all geometrical isomers. An organic chemist of ordinary skill would understand the formula for lutein to include all cis and trans isomeric forms." (Dr. Schwartz Report, Doc. # 164 at 6). The purity calculation should be based on the percentage of lutein and not based only on the percentage of trans-lutein.

The Court adopts Plaintiffs' position on this point. All lutein isomers have the exact chemical formula as claimed in claim 1 of the '714 patent; they differ only in the way those chemical elements are arranged in three-dimensional space. (Doc. # 161 at 15). Thus, "Lutein" as used in claim 1 is all isomers of lutein, and not just "trans-lutein."

2. **"Substantially pure" and "substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract"**

To ascertain what the claim terms "substantially pure" and "substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract" mean, the Court must determine how lutein purity is measured.

Plaintiffs assert that the phrases "substantially pure" and "substantially free from other carotenoids and chemical impurities" must be read together and that, together, these phrases mean that "(1) lutein makes up at least 90% of the total carotenoids that are contained in the lutein composition, and (2) the proportion of non-carotenoid chemical impurities compared to total carotenoids in the lutein composition is sufficiently small to permit crystallization of the composition." (Doc. # 244 at 3).

Defendants, on the other hand, argue that the 90% lutein purity is measured in relations to the crystals as a whole, not just the carotenoid composition of those crystals. (Doc. # 103 at 21-22). Thus, Defendants request that the Court consider noncarotenoids, such as fats and waxes, when evaluating lutein purity.

In the PIVEG litigation, the alleged infringer advanced an argument that is very similar to Defendants' argument in the present case, which the district court in PIVEG rejected. The district court in the PIVEG case held that the phrase "substantially pure lutein" must refer to "an amount of lutein in the 'carotenoid composition.'" Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A., 301 F.Supp.2d 970, 985 (S.D. Iowa 2004). The court explained:

Claim construction insists that "the same word appearing in the same claim should be interpreted consistently." Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1345 (Fed. Cir. 1998). The language of claim 1 states: "The carotenoid composition consisting essentially of substantially pure lutein crystals derived from plant extracts." This clearly indicates that "substantially pure lutein" must refer to an amount of lutein in the "carotenoid composition." This contradicts PIVEG's interpretation which would include measurement of lutein against all other materials present and would not be limited to other carotenoids present. Contrary to PIVEG's assertions, the three phrases are not actually separate but together indicate the protected level of lutein purity in the carotenoid composition. Thus, lutein purity is to be measured as related to the carotenoid composition and the claim requires the lutein to be substantially free from other carotenoids and chemical impurities.

301 F.Supp.2d at 985 (emphasis in original).

This Court agrees that, when evaluating lutein purity, the Court should consider the percentage of lutein against the percentage of other carotenoids. Residual plant matter, fatty acids, and waxes that are not carotenoids are not to be considered in the "carotenoid composition."

In a similar argument, Defendants contend that non-carotenoids (the same residual plant matter, fatty acids, and waxes) can undermine the lutein purity of a lutein crystal. Plaintiffs respond that the inventor, Dr. Khachik, recognized that lutein crystallization typically removes some, but not all, of these harmless "background" plant constituents. In

fact, a lutein crystal can have up to 30% of these noncarotenoid constituents. (Dr. Khachik Dep., Doc. # 181-5, Ex. D at 65-71).⁵

The Court agrees with Plaintiffs that if Defendants' claim construction on the issue of lutein purity were adopted, "nobody would be practicing under the '714 patent, including Kemin." (Doc. # 181 at 13). It cannot be disputed that Plaintiffs' as well as Defendants' lutein products contain the aforementioned noncarotenoid plant materials in meaningful quantities. As stated by Zoraida DeFreitas, Ph.D., "if lutein purity were measured against the total mass of the purified product, as OmniActive advocates, Kemin's own free lutein products would have only 74.4 to 80% lutein purity." (Dr. DeFreitas Decl. at ¶ 5, Doc. # 181-6 at Ex. E). Thus, under Defendants' proposed construction, Kemin's own products would not fall within the ambit of Plaintiffs' patent.

The Federal Circuit explains that "[A] claim interpretation that would exclude the inventor's device is rarely the correct interpretation." Modline Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1550 (Fed. Cir. 1996),

⁵However, at 49% noncarotenoid constituents, there would be no crystal. (Dr. Khachik Dep. Doc. # 181, Ex. D at 65-71).

abrogated on unrelated grounds by Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000).

Stated another way, patent claims should not be construed in a manner that excludes the very invention that the patent was intended to protect. Osram GmbH v. Int'l Trade Com'n, 505 F.3d 1351, 1358 (Fed. Cir. 2007)(rejecting proposed claim construction because it "would exclude the OSRAM products that the patents were designed to cover").

After due consideration, the Court adopts Plaintiffs' position as follows:

The phrases "substantially pure" and "substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract" must be read together. Together, these phrases mean that (1) lutein makes up at least 90% of the total carotenoids that are contained in the lutein composition, and (2) the proportion of non-carotenoid chemical impurities compared to the total carotenoids in the lutein composition is sufficiently small to permit crystallization of the composition.

(Doc. # 244 at 3).

3. "No Traces of Toxic Chemicals"

In the jointly submitted claim construction stipulation, the parties set forth their differing positions regarding "no traces of toxic chemicals" as follows:

OmniActive's position: "No traces of toxic chemicals" means no detectable amounts of any toxic chemicals as measured by methods known to persons

of ordinary skill in the art at the time the patent application was filed in 1994.

Kemin's position: "No traces of toxic chemicals" means no detectable amounts of any toxic chemicals as measured by a method that would have been used in 1994 by a person of ordinary skill in the art who was preparing a product suitable for human consumption.

(Doc. # 244 at 2).

The parties have come a long way toward reaching an agreement concerning what "no traces of toxic chemicals" means. Originally, Defendants asserted that "no traces of toxic chemicals" meant exactly that - no traces of any toxic chemicals using a state-of-the-art method of detection available in 2008. At this point in the litigation, Defendants have retreated from this argument.

The parties appear to agree that the level of detection for toxic chemicals, including hexane, should be measured by the science that was available to a person of ordinary skill in the art in 1994.⁶ The Court agrees with the parties on

⁶ The parties take varying positions throughout their filings concerning whether the applicable year is 1993 or, rather, 1994. For instance, in Plaintiffs' claim construction brief filed on February 17, 2009, Plaintiffs focus on 1993. (Doc. # 181 at 19). In the parties' stipulation on claim construction, the parties agree that 1994 is the relevant year. (Doc. # 244 at 2). The Court determines that 1994 is the applicable year because that is the year that the parties agreed to in the most recent, stipulated filing. (Doc. # 244).

this point.

The Federal Circuit explained in SmithKline Beacham Corp. v. Apotex Corp., 403 F.3d 1331, 1338 (Fed. Cir. 2005)(en banc), "The court [must] place the claim language in its proper technological and temporal context." It is not appropriate to apply a level of detection threshold considered to be state of the art in 2009, to an invention formed in 1994. San Huan New Materials High Tech, Inc. v. U.S. Int'l Trade Comm'n, 161 F.3d 1347 (Fed. Cir. 1998). See also Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005)(en banc)("We have made clear . . . that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application").

However, the Court must delve deeper into the analysis. Looking closely at the parties' respective positions, the Court determines that there are three issues within the term "no traces of toxic chemicals" that the parties continue to dispute: (1) whether the Court must take into consideration what is "suitable for human consumption," (2) whether an ordinary person would either "use" or "know" of the method of

detection for toxic chemicals, and (3) what method of detection applies.

i. Suitable for Human Consumption

Defendants argue that what is "suitable for human consumption" does not factor into the determination of what "no traces of toxic chemicals" means.

In Plaintiffs' initial brief and reply brief on claim construction (Doc. # 161, 181), Plaintiffs never once requested that "suitable for human consumption" be added into the definition of "no traces of toxic chemicals." Instead, Plaintiffs argued in their initial and reply claim construction briefs "the term 'no traces of toxic chemicals' means 'no traces of toxic chemicals taking into account the limits of detection for a method that would have likely been relied upon by an organic chemist for that product in 1993.'" (Doc. # 161 at 20; Doc. # 181 at 19).

As far as this Court can ascertain, Plaintiffs inserted "suitable for human consumption" on the eve of the Markman hearing in the parties claim construction stipulation. (Doc. # 244 at 2). During the Markman hearing, Plaintiffs pointed to many references in the '714 patent that discuss the necessity for creating lutein that is suitable for human consumption: "To date, pure lutein suitable for human use has

not been commercially available for use as a chemopreventive agent in clinical trials. Pure lutein, free from chemical contaminants and suitable for human consumption, is needed to design and conduct proper human intervention studies." ('714 patent Column 2, Lines 5-10) (emphasis added). "Another objective of the present invention is to provide purified lutein in crystalline form such that it is acceptable for human consumption and use in cancer prevention trials and treatments without causing toxic side effects due to residual impurities." ('714 patent Column 3, Lines 17-21) (emphasis added).

Nevertheless, the Federal Circuit expressly stated in the PIVEG case that it was "error" for the district court to include the "suitable for human consumption" language in its construction of claim 1 of the '714 patent. Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro, S.A., 93 F. App'x 225, 232 (Fed. Cir. Mar. 17, 2004). The district court, in PIVEG, modified its claim construction by deleting "suitable for human consumption" and the Federal Circuit affirmed. 357 F.Supp.2d 1105, 1122 (S.D. Iowa 2005), aff'd in relevant part, 464 F.3d 1339 (Fed. Cir. 2006).

Since the beginning of this case, Plaintiffs have argued that this Court should follow the PIVEG claim construction.

This Court is not inclined to insert "suitable for human consumption" into the definition of "no traces of toxic chemicals" in derogation of the Federal Circuit's clear instructions.

ii. "Known" or "Used"

In the context of determining how persons of ordinary skill in the art would go about detecting toxic chemicals, such as hexane, the parties disagree as to whether the chemicals are detected by "methods known to persons of ordinary skill in the art" or whether such chemicals are detected by "a method that would have been used" by a person of ordinary skill in the art. (Doc. # 244 at 2)(emphasis added).

As posited by Plaintiffs, "the dispute boils down to a choice between the theoretically best available method as opposed to the method actually used by persons of ordinary skill in the art at the time of the invention." (Doc. # 239 at 3)(emphasis in original). In support of the argument that "no traces of toxic chemicals" means "no detectable amounts of any toxic chemicals as measured by a method that would have been used in 1994 by a person of ordinary skill in the art . . .," Plaintiffs persuasively contend that "a person of ordinary skill in making purified lutein under this patent would use a

readily available testing method that was sufficient to make sure the product was suitable for its stated goals. She or he would not research endlessly to determine if some better technology existed somewhere in the world that, with unlimited time and resources, she or he might be able to access." (Doc. # 239 at 5).

The Court is persuaded by Plaintiffs' common sense approach to this issue. Defendants' arguments on this point -- that toxic chemicals should be measured by a method "known" -- are nebulous and could lead to confusion in this already complex case. Defendants will have an opportunity to argue to the jury that their proffered method of detecting toxic chemicals would have been "used" by a person of ordinary skill in the art in 1994.⁷

⁷ Without determining which method of detecting toxic chemicals applies, the Court determines that persons of ordinary skill in the art would likely "know" of several methods for detecting toxic chemicals, ranging from the most simple (such as using the human senses of sight, touch, smell, and taste) to the most complex (likely some variation of gas chromatography mass spectrometry (GC-MS) coupled with flame ionization detection (GC-FID)). As stated by Dr. Schwarz, "Many methods have been developed to measure residual solvent concentrations, and therefore, methods with varying sensitivities have been published in the scientific literature." (Dr. Schwartz Report, Doc. # 164 at 25). A person of ordinary skill in the art would likely not use the most advanced, expensive, or cutting-edge method of detection in every situation. For instance, Dr. Khachik used nuclear magnetic resonance (NMR) to test for hexane. Dr. Khachik's

iii. Method of Detection

The last point of contention regarding the definition of "no traces of toxic chemicals" concerns how a person of ordinary skill in the art would go about detecting toxic chemicals, namely hexane. Although the parties have fully briefed the issue, the Court declines to address it at this juncture. A jury, rather than this Court, should decide what method would have been used in 1994, by the person of ordinary skill in the art who was preparing a purified lutein product.⁸ After the jury makes this factual determination, the Court will be able to answer the question of "how much hexane must be present to take a lutein product outside the scope of the '714 patent." (Doc. # 239 at 2).

Accordingly, the Court clarifies the term "no traces of toxic chemicals" to mean no detectable amounts of any toxic chemicals as measured by a method that would have been used in 1994, by a person of ordinary skill in the art.

"educated guess is that this method had a limit of detection of 30-40 parts per million. The jury must determine what method a person of ordinary skill in the art would use to detect toxic chemicals in 1994, when making purified lutein.

⁸Plaintiffs agree that this issue should be left to the jury, and Plaintiffs argue "OmniActive appears to want this Court to decide fact questions under the guise of claim construction." (Doc. # 181 at 2). The Court will not invade the province of the jury by deciding factual issues.

V. Factual Issues Precluding Summary Judgment

Defendants assert a judgment of noninfringement is appropriate because their products (1) contain hexane (a toxic chemical) and (2) contain lutein crystals that are less than 80% pure. However, after due consideration of the file, the Court determines that a summary judgment of noninfringement in Defendants' favor is not appropriate. As stated in Novartis Corp., 271 F.3d 1043, 1046 (Fed. Cir. 2001): "Summary judgment is appropriate when, after opportunity for discovery and upon motion, there is no genuine dispute of material fact for trial and one party is entitled to judgment as a matter of law." Id. Defendants have not met their burden.

A. Laboratory Testing of Defendants' Products

Plaintiffs argue that there is sufficient evidence from which a reasonable jury could find that Defendants infringed claim 1 of the '714 patent. Specifically, Plaintiffs argue, a reasonable jury could determine (1) that Defendants sold purified lutein products in the United States where the lutein is greater than about 90% pure as related to the carotenoid composition, and (2) that those products have no traces of hexane that would have been detected by a person of ordinary skill in the art in 1994. Plaintiffs provided the Court with volumes of reports in support of their position, including,

but not limited to reports from Covance and Alliance Labs as well as Defendants' self-reporting documents.

Concerning lutein purity, Dr. Schwartz has reviewed the lab reports and provides the following summary:

Analytical results performed by Covance of OmniActive products were discovered to contain a lutein carotenoid composition of greater than 90% and significantly less than 10% other carotenoids. Specific batches are Lutemax Free Lutein Oil Suspension containing 94.0% lutein and 6.0% other carotenoids (Sample Code PDO/070305, Item Code 26507, Covance Ex. 3) and Free Lutein Vegetarian Beadlets containing 92.2% lutein and 7.8% other carotenoids (Sample Code PD 260207151).

Analytical results performed by Alliance Technologies LLC, of OmniActive beadlets (Lot # MRLB-122A) showed a lutein purity of 93.8% and 6.2% of other carotenoids (Report Alliance Technologies, December 12, 2008).

OmniActive's Certificates of Analysis cite lutein content of greater than 90% for Lutemax Free Lutein Oil Suspension . . . and Lutemax Free Lutein Crystal. . . .

Results of Kemin Health Laboratories analysis of OmniActive's Lutemax Free Lutein Oil Suspension (Sample Code PD-050109) indicate a lutein carotenoid composition of 91.4% and 8.6% of other carotenoids (KEM102414-KEM102415).

Results of independent analytical testing conducted by Dr. Carr indicate a lutein carotenoid composition at 92.3 percent and significantly less than 10% of other carotenoids.

(Dr. Schwartz Report, Doc. # 164 at 19-20).

Dr. Schwartz also provides a detailed analysis of hexane

content in Defendants' products. (Dr. Schwartz Report, Doc. # 164 at 42).

The lab reports analyzing Defendants' products are only one piece of the puzzle. The Court has reviewed the reports in question but determines that it is appropriate to deny summary judgment because factual issues preclude a finding of noninfringement.

Among other things, a jury must determine how a person of ordinary skill in the art would go about detecting hexane or other toxic chemicals in a purified lutein product in 1994. Upon due consideration, the Court finds that a jury, rather than this Court, must determine whether Defendants' products infringe the '714 patent.

Accordingly, it is

ORDERED ADJUDGED and DECREED that:

OmniActive Health Technologies, Inc.'s Motion for Summary Judgment of Noninfringement (Doc. # 103) is **DENIED**.

DONE and **ORDERED** in Chambers in Tampa, Florida, this 27th day of September 2009.


VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE

Copies:
All Counsel of Record