

United States District Court,  
S.D. Iowa, Central Division.

**KEMIN FOODS, L.C., The Catholic University of America,**  
Plaintiff.

v.  
**PIGMENTOS VEGETALES DEL CENTRO S.A. DE C.V,**  
Defendant.

**Jan. 13, 2004.**

**Background:** Owner and licensee of patents for purified lutein crystals and process for creating them sued competitor for infringement.

**Holdings:** Construing claims, the District Court, Gritzner, J., held that:

- (1) requirement that crystals be "substantially pure," meant that 90 percent or more of carotenoid composition had to be lutein, and
- (2) process patent claim did not require that called-for steps be taken in sequential order.

Claims construed.

See also 240 F.Supp.2d 963.

5,382,714, 5,648,564. Construed.

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Brian G. Pingel, Michael A. Dee, Camille L. Urban, Brown, Winick, Graves, Gross, Baskerville & Schoenebaum PLC, West Des Moines, IA, for Defendant.

## **ORDER ON CLAIM CONSTRUCTION**

**GRITZNER, District Judge.**

This matter is before the Court for construction of disputed claims of the patents-in-suit. Oral argument was

heard in a *Markman* FN1 Hearing held on November 25, 2003. Attorneys for the Plaintiff are Susan Knoll, Scott Clark, and Roger Stetson; attorneys for the Defendant are Brian Pingel, Michael Dee, and Camille Urban.

FN1. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

### **Procedural History**

The Plaintiffs, Kemin Foods, L.C. ("Kemin") and The Catholic University of America, filed an infringement action against the Defendant, Pigmentos Vegetales del Centro S.A. de C.V. ("PIVEG"), on July 9, 2002. The lawsuit alleges infringement of two patents held by Kemin, U.S. Patent No. 5,382,714 ("the '714 patent") and U.S. Patent No. 5,648,564 ("the '564 patent"), by PIVEG. In turn, PIVEG has alleged several counterclaims against Kemin relating to the patents-in-suit.

Kemin also sought a preliminary injunction to prevent PIVEG from continuing to make, use, import, or sell its purified lutein crystals from plant extracts and from practicing the process of extraction protected by the '564 patent, and importing the product thereof into the U.S. during the pendency of this lawsuit. The Court ruled on this motion in an order filed January 2, 2003, and as supplemented on January 7, 2003. The Court granted the motion for preliminary injunction as to the '714 patent and denied the motion as to the '564 patent. Enforcement of the preliminary injunction has been stayed and is currently pending review before the Federal Circuit.

Trial is currently scheduled for September 13, 2004. In preparation, the parties have presented briefs and supplemental briefs on the issue of claim construction. As fully discussed below, the interpretation of a patent's claims, also known as the construction of claims, is a matter solely within the province of the Court to determine as a matter of law.

### **Background Facts**

Kemin is an Iowa limited liability company with its principal office in Des Moines, Iowa. Kemin produces the product at issue in this lawsuit, purified lutein crystals. This product is protected by the '714 patent. Kemin currently produces the purified lutein crystals protected by the '714 patent using in part an extraction process protected by the '564 patent.

PIVEG is a Mexican company located primarily in Celaya, Mexico. Historically, the primary business objective of PIVEG has been making pigments for the poultry industry.

Kemin produces and distributes purified lutein crystals in oils, powders, and beadlet form. While other companies market and sell so called "lutein" type products, in reality, these products do not contain the purified lutein crystals protected by the '714 patent. Rather, these products contain lutein esters, which are not purified lutein, are not comprised of the same chemical compound as that protected by the '714 patent, and do not provide the advantages associated with Kemin's purified lutein crystals. These products do not infringe on the '714 patent.

Recently, PIVEG has begun to market and offer for sale within the U.S. certain powders, beadlets, and oils containing purified lutein crystals. Upon becoming aware of PIVEG's products, Kemin obtained samples and subjected them to chemical testing. These tests revealed that PIVEG's products contained the identical

chemical compound of purified lutein crystals that are protected by the '714 patent. Additional chemical analysis demonstrated to Kemin that PIVEG's products also contained propylene glycol. According to Kemin, PIVEG's products infringe the '714 patent and possibly the '564 patent. Based on these findings, Kemin filed suit against PIVEG alleging infringement of both the '714 and '564 patents.

PIVEG responds to these allegations by explaining that they have marketed lutein for use primarily in the poultry industry since 1978. PIVEG began creating and providing "poultry-grade" lutein, which was included in poultry feed, after it was discovered in the 1970's that lutein intensified the yellow of the yolk of a chicken egg and increased the yellow color of chicken meat.

During the late 1980's and early 1990's, research scientists began speculating that anti-oxidants could be beneficial to human health, especially with respect to cancer. Additionally, around 1994, lutein was found to promote human eye health by decreasing the incidence of macular degeneration, one of the leading causes of vision loss in the elderly. Based on these discoveries, in the early 1990's PIVEG developed its own process for obtaining and purifying lutein suitable for human consumption, this process being an extension of the process PIVEG had used to produce lutein for poultry feed additives since the mid 1980's.

Ultimately, PIVEG counters Kemin's infringement allegations by arguing patent '564 is not valid, or is unenforceable; that PIVEG does not infringe patent '564; that the '714 patent is invalid (having been anticipated by the prior art); the '714 patent is unenforceable (due to Kemin's inequitable conduct in obtaining the '714 patent in not disclosing relevant and material prior art to allow the PTO office to make the necessary determinations regarding whether a patent should issue); and alternatively, that PIVEG does not infringe the '714 patent. PIVEG has also filed four counterclaims against Kemin.

## Analysis

### A. Patent Infringement

[1] A patent is a legal document that defines the metes and bounds of the patentee's invention. *See Engineered Prods. Co. v. Donaldson Co.*, 165 F.Supp.2d 836, 871-72 (N.D.Iowa 2001) ("A patent describes the exact scope of an invention so as to 'secure to [the patentee] all to which he is entitled, [and] to apprise the public of what is still open to them.' ") (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996) ("*Markman II*")). This is done in the specification, which must fully and clearly describe the invention, and in the claims, which set out the scope of the of the patent and are included at the end of the written description. *Markman II*, 517 U.S. at 373, 116 S.Ct. 1384. "Victory in an infringement suit requires a finding that the patent claim 'covers the alleged infringer's product or process,' which in turn necessitates a determination of 'what the words in the claim mean.' " *Markman II*, 517 U.S. at 374, 116 S.Ct. 1384 (quoting H. Schwartz, *Patent Law and Practice* 80 (2d ed.1995)). Thus, the determination of whether the patent has been infringed is a two-step process. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996) ("*Markman I*").

[2] [3] The first step is the interpretation of the patent, i.e., the meaning and scope of the patentee's claims. *Id.* This is a legal determination that is solely within the province of the court. *Id.* at 979; *see also Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed.Cir.1999) ("Accordingly, it falls upon the district court to discern the meaning of the claim language."). The second step consists of comparing the properly construed claims with the accused product. *Markman I*, 52 F.3d at 976; *see also Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1570 (Fed.Cir.1992). If the accused

product or process clearly falls within at least one of the claims, infringement has occurred. *Graver Tank & Mfg. Co. v. Linde Air Products, Co.*, 339 U.S. 605, 607, 70 S.Ct. 854, 94 L.Ed. 1097 (1950). This is a question of fact, ultimately to be resolved by the fact finder. *Markman I*, 52 F.3d at 976; *Minnesota Mining & Mfg. Co.*, 976 F.2d at 1570.

[4] In a limited manner, the Court already considered the meaning of the asserted claims of the '714 and '564 patents when it ruled on Kemin's motion for preliminary injunction. FN2 The Court is not bound by its findings at the preliminary injunction stage in its subsequent claim construction. *See Univ. of Texas v. Camenisch*, 451 U.S. 390, 395, 101 S.Ct. 1830, 68 L.Ed.2d 175 (1981); *see also Oakley v. Sunglass Hut, Int'l*, 316 F.3d 1331, 1345 n. 3 (Fed.Cir.2003) (cautioning district courts on using claim constructions based on a preliminary record). This is because the court's understanding of the technology of the case evolves as the case develops. *See Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed.Cir.2002).

FN2. In its orders ruling on Kemin's motion for preliminary injunction, the Court finds Kemin showed a likelihood of success as to the issue of infringement on the '714 patent but not on the '564 patent. The Court found the claimed composition required lutein crystals from plant extracts with a purity level of 90 percent or greater and/or suitable for human consumption.

## **B. The Patents-In-Suit**

As noted, there are two patents at issue in this case. Briefly, the '714 patent describes and claims a composition of substantially pure lutein. The '714 patent also describes a process to arrive at this composition though Kemin has not alleged infringement of this portion of the '714 patent, namely, claims 5-20. The '564 patent describes a process for forming, isolating, and purifying xanthophyll crystals from certain plants, including lutein from marigold flower petals. This is another process used by Kemin to achieve the composition protected by the '714 patent.

### **1. Technology and Terminology**

In the following paragraph, the Court briefly includes some terminology common to the patents-in-suit, their claims, and the filed briefs relating to the construction of those claims. This discussion of technology and terminology is beneficial in understanding the issues presented to the Court.

Carotenoid refers to a class of yellow to red pigments. It includes hydrocarbons (carotenes) and their oxygenated, alcoholic derivatives (xanthophylls). Carotenoids are abundant in fruits and vegetables and include beta-carotene, alpha-carotene, lycopene, and zeaxanthin. Lutein is a carotenoid typically present in plant chromoplasts as lutein esters, i.e., lutein chemically bonded to long chains of fatty esters. Lutein is found in certain fruits and vegetables as well as in the flower petals of marigolds. Lutein esters can be extracted from the plant material. This results in a plant extract containing lutein esters. The plant extracts are oleoresins. Saponification is the process by which the bonds attaching the lutein to the chain of fatty esters in the plant extract are broken, leaving free lutein. Free lutein refers to lutein that has been separated from the chain of fatty esters.

The following terms are defined as relating to the patents-in-suit. UV/visible spectrophotometry measures the concentration of lutein in the whole product as measured by the amount of light absorbed at a given wavelength. High Performance Liquid Chromatography ("HPLC") provides a way to separate carotenoids from each other and then measure the amount of each carotenoid. This provides a profile of just the

carotenoids present in a substance and their relationship to each other. Nuclear Magnetic Resonance ("NMR") is generally utilized to determine the structure of compounds. It has relatively high detection limits and is not commonly used for trace analysis.

## **2. The '714 Patent**

The '714 patent is entitled "Process of Isolation, Purification, and Recrystallization of Lutein from Saponified Marigold Oleoresin and Uses Thereof." It was issued on January 17, 1995, and protects substantially pure lutein crystals. Lutein is a carotenoid, which relates to any class of yellow to red pigments including the carotenes and the xanthophylls, both naturally occurring in certain plants. Various fruits (orangish/red fruits like mango, papaya, peaches and orangish vegetables like butternut and acorn squash) and green leafy vegetables (spinach, kale, brussel sprouts, broccoli, green beans green peas) contain lutein. Lutein has also been discovered in the flower petals of marigolds.

Over the last few years, lutein has been widely acclaimed for its antioxidant properties, and its effect on the macular area of the eyes. Kemin points out that the benefits that have been analyzed arise only from free form lutein, as opposed to esters (which is a completely different chemical compound) or oleoresin (which is a mixture of oils and resins from plants). Kemin points out that while the '714 patent protects free form lutein, other products on the market labeling themselves as "lutein" are not purified free form lutein crystals, but are naturally occurring lutein esters, a different chemical compound, and thus non-infringing.

## **3. The '564 Patent**

The '564 patent is entitled "Process for the Formation, Isolation and Purification of Comestible Xanthophyll Crystals from Plants." It was issued on July 15, 1997 and protects the process Kemin currently uses in part to produce the purified lutein crystals protected by the '714 patent. Specifically, purified xanthophylls (a yellow carotenoid pigment such as lutein) are extracted through a process that does not use harmful organic solvents. The resulting lutein product does not exceed safe toxicity levels for human consumption.

The process protected by the '564 patent uses non-harmful propylene glycol and water extraction, resulting in lutein crystals without any residue of potentially harmful organic solvent, and therefore suitable for human consumption. Kemin's purified lutein crystals have achieved the status of "Generally Recognized As Safe" under the Federal Food, Drug, and Cosmetic Act. Prior processes for obtaining purified lutein crystals from certain plant extracts were not cost effective.

## **C. General Rules of Claim Construction**

[5] The Court is to construe the terms of the claims as "one of ordinary skill in the art at the time of the invention would have understood the term to mean." Markman I, 52 F.3d at 986. The person of ordinary skill in the art at the time of the invention is a hypothetical person based on numerous factors. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed.Cir.1986). This person is presumed to have a level of general knowledge regarding the art commensurate with their level of skill. *Id.*

The relevant time frame would be 1994 for the '714 patent and 1995 for the '564 patent, the time when the respective patent applications were filed. Kemin asserts the person of ordinary skill in the art for the '714 patent would possess a level of skill consistent with a Ph.D. in Chemistry or Organic Chemistry with at least two years of work or academic experience in Organic Chemistry. Kemin further asserts the person of ordinary skill in the art for the '564 patent would possess a level of skill consistent with a B.S. in Chemical

Engineering or Chemistry with knowledge of applied chemistry and chemical process technology. PIVEG does not oppose these assertions in its filings and the Court adopts these as the standards of the person of ordinary skill in the art for purposes of construing the claims in issue.

[6] [7] [8] Claim interpretation begins with an examination of the intrinsic evidence, *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996), including the written description, consisting of the claims and the specification, along with the prosecution history if it is in evidence. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed.Cir.2002); *Vitronics Corp.*, 90 F.3d at 1582 ("It is well-settled that ... the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history."). "In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term." *Vitronics*, 90 F.3d at 1583. The claim interpretation should be consistent with and further the purpose of the invention. *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1160 (Fed.Cir.1997). In addition, the claims must be construed consistent with the patent document as a whole. *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 347 F.3d 1367, 1371 (Fed.Cir.2003); *see also* *United States v. Adams*, 383 U.S. 39, 49, 86 S.Ct. 708, 15 L.Ed.2d 572 (1966) (finding it is "fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention").

While the entire patent document may be used in construing the claims, "it is the *claims* that measure the invention." *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed.Cir.1985); *see also* *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed.Cir.2002) (noting "the claim requirement presupposes that a patent applicant defines his invention in the claims"). Hence, the court should first look to the words of the claim to define the scope of the invention. *Vitronics Corp.*, 90 F.3d at 1582; *see also* *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed.Cir.1998); *Phonometrics, Inc. v. Northern Telecom Inc.*, 133 F.3d 1459, 1464 (Fed.Cir.1998).

[10] [11] In order to determine the ordinary meaning of a claim term, the court may look to "a variety of sources, including the claims themselves, ... other intrinsic evidence including the written description and the prosecution history, ... and dictionaries and treatises." *FN3 Teleflex, Inc. v. Ficosa N.A. Corp.*, 299 F.3d 1313, 1325 (Fed.Cir.2002) (internal citations omitted). A court must also look to other claims using the same term and interpret like terms consistently in all claims. *CVI/Beta Ventures, Inc.*, 112 F.3d at 1159.

FN3. In particular, while once considered technically extrinsic evidence, dictionaries have a special place and may be considered alongside intrinsic evidence to determine the ordinary meaning of claim terms. *Bell Atl. Network Servs. v. Covad Communications Group*, 262 F.3d 1258, 1267 (Fed.Cir.2001) (citing *Vitronics Corp.*, 90 F.3d at 1584 n. 6). In fact, following a recent Federal Circuit decision, dictionaries and treatises are to be considered particularly useful to a court in determining the ordinary and customary meaning of language used in a patent claim. *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202-03 (Fed.Cir.2002), *cert denied*, 538 U.S. 1058, 123 S.Ct. 2230, 155 L.Ed.2d 1108 (2003).

[12] While it is assumed the words used have their ordinary and accustomed meaning, examination of the specification, prosecution history, and other claims may indicate that the inventor intended a different meaning. *See* *Vitronics Corp.*, 90 F.3d at 1582; *see also* *IMS Technology, Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1433 (Fed.Cir.2000) (finding no special definition of a term inconsistent with its ordinary meaning where the patentee did not use the term and specify an alternate meaning in the specification).

This is because "a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." *Vitronics Corp.*, 90 F.3d at 1582; *see also* *Apple Computer, Inc. v. Articulate Sys., Inc.*, 234 F.3d 14, 21 n. 5 (Fed.Cir.2000) (finding patentee must deliberately and clearly point out in the patent specification or prosecution history how the terms differ from the ordinary meaning if the patentee desires to define a claim term in an alternate way); *Renishaw*, 158 F.3d at 1249 (same).

[13] If there is some dispute as to the meaning of a term, the specification "is the single best guide to the meaning of the disputed term." *Vitronics Corp.*, 90 F.3d at 1582; *see also* *Teleflex, Inc.*, 299 F.3d at 1326 ("claims must be read in view of the specification"); *Comark Communications Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed.Cir.1998); *General American Transp. Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 770 (Fed.Cir.1996). This is because the specification "contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it" making the specification "highly relevant to the claim construction analysis." *Vitronics*, 90 F.3d at 1582. In fact, when claim terms are unclear or ambiguous, a court may "use statements in the written description to confine or otherwise affect a patent's scope," but must point to terms within the claim to draw in those statements. *Renishaw*, 158 F.3d at 1248.

In addition, the court can also consider, if in evidence, the patent's prosecution history. *Vitronics*, 90 F.3d at 1582. The prosecution history can further help the court construe the patent's claims because it contains the record of proceedings before the Patent and Trademark Office. *Id.* This may include "express representations made by the applicant regarding the scope of the claims" and examination of prior art. *Id.* "The prosecution history is often helpful in understanding the intended meaning as well as the scope of technical terms, and to establish whether any aspect thereof was restricted for purposes of patentability." *Vivid Technologies, Inc. v. American Sci. & Eng'g, Inc.*, 200 F.3d 795, 804 (Fed.Cir.1999) (citing *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed.Cir.1995)).

[14] A court should not, however, read into a claim a limitation that it does not contain. *See Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 871 F.2d 1054, 1065 (Fed.Cir.1989); *see also* *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1362 (Fed.Cir.2000) (quoting *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1348 (Fed.Cir.1988), for the rule that a limitation in the written description cannot be read into a claim that does not appear in the claim); *Markman I*, 52 F.3d at 980 (stating prosecution history cannot be used to enlarge diminish, or vary limitations in the patent's claims); *SRI Int'l*, 775 F.2d at 1121 (finding that limitations appearing in the preferred embodiment of the invention as described in the specification should not be read into a claim that does not contain any such limitation). In other words, the court should neither broaden nor narrow the claims and give the patentee something other than that set forth in the claims. *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 619 (Fed.Cir.1995) (citing *Autogiro Co. of America v. U.S.*, 181 Ct.Cl. 55, 384 F.2d 391, 396 (1967)). Moreover, when some of the claims are broad while others are narrow, the narrow claim limitations should not be read into those claims that are more broad. *Transmatic, Inc. v. Gulton, Indus., Inc.*, 53 F.3d 1270, 1277 (Fed.Cir.1995) (quoting *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574 (Fed.Cir.1985)).

#### **D. Role of Extrinsic Evidence**

Extrinsic evidence includes prior art not cited during prosecution of the patent, dictionary definitions of disputed claim language, treatises, and expert opinions. *Vitronics Corp.*, 90 F.3d at 1584. While the Federal Circuit has "made strong cautionary statements on the proper *use* of extrinsic evidence," *Key Pharms. v.*

Hercon Labs. Corp., 161 F.3d 709, 716 (Fed.Cir.1998) (citing Vitronics, 90 F.3d at 1583), a court is not restricted in its ability to *hear* extrinsic evidence. *Id.* A court may take into consideration such evidence in certain circumstances, but it is entitled to very little weight. *See* Engineered Prods. Co., 165 F.Supp.2d at 874 (citing Vitronics, 90 F.3d at 1584, and Markman I, 52 F.3d at 978-79).

[15] "While a judge is well-equipped to interpret the legal aspects of the document, he or she must also interpret the technical aspects of the document, and indeed its overall meaning, from the vantage point of one skilled in the art." Pitney Bowes, 182 F.3d at 1309. Accordingly, extrinsic evidence may be considered by the court to assist it "in understanding the underlying technology of a claimed invention or the meaning of technical terms with which the court is unfamiliar," Engineered Prods. Co., 165 F.Supp.2d at 874; *see also* Pitney Bowes, 182 F.3d at 1309, and to aid in construction of the claim terms if, and only if, the intrinsic evidence is insufficient to enable the court to properly construe the disputed terms. Vitronics Corp., 90 F.3d at 1583.

The court can rely on extrinsic evidence such as expert testimony to assist the court in understanding the underlying technology.FN4 Iowa State Univ. Research Found. Inc., 291 F.Supp.2d at 885. Extrinsic evidence may also be used to guide the court to an understanding of unfamiliar technical terms. Engineered Prods. Co., 165 F.Supp.2d at 874; *see also* Merck & Co., 347 F.3d at 1372 (finding "it is not prohibited to provide the opinions and advice of experts to explain the meaning of terms as they are used in patents and as they would be perceived and understood in the field of an invention") (citing Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314 (Fed.Cir.2003), and Pitney Bowes, 182 F.3d at 1309).

FN4. "[T]estimony on the *technology* is far different from other expert testimony, whether it be of an attorney, a technical expert, or the inventor, on the *proper construction* of a disputed claim term...." Vitronics, 90 F.3d at 1585.

[16] A court may also review extrinsic evidence to ensure the interpretation of a claim term is consistent with the way that term is used in a technical field. Pitney Bowes, 182 F.3d at 1309 ("consultation of extrinsic evidence is particularly appropriate to ensure that [the court's] understanding of the technical aspects of the patent is not entirely at variance with the understanding of one skilled in the art."); *see e.g.*, Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1346 (Fed.Cir.2003) (finding district court did not abuse discretion in considering extrinsic evidence when it "consulted extrinsic evidence to ensure that its interpretation of the claim language was not inconsistent with the understanding in the technical field as of the filing date of the patent."). The decision to receive extrinsic evidence to aid in understanding the patent is discretionary. *See* EZ Dock, Inc. v. Schafer Sys., Inc., 2003 WL 163718, (D.Minn.) (citing Markman I, 52 F.3d at 980).

A court may also turn to extrinsic evidence if the intrinsic evidence does not resolve all ambiguities regarding the meaning of a disputed term. Vitronics, 90 F.3d at 1583. "In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence." *Id.* In any case, where the intrinsic evidence resolves any ambiguities in the claim language, extrinsic evidence should not be used to alter or change the meaning of that language. *Id.*; *see also* Iowa State Univ. Research Found. Inc., 291 F.Supp.2d 883, 885, 891, 892 (S.D.Iowa) ("Given the conclusiveness of the intrinsic evidence in determining the meaning of the words ..., the Court finds it unnecessary and improper to engage in an analysis of any extrinsic evidence, including expert testimony.").

[17] Extrinsic evidence relating to the proper construction of a claim term "may only be relied upon if the patent documents, taken as a whole, are insufficient to enable the court to construe disputed claim terms." *Pitney Bowes*, 182 F.3d at 1308-09 (quoting *Vitronics*, 90 F.3d at 1585); *see also* *Storage Technology Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 832 (Fed.Cir.2003) (citing *Vitronics*, 90 F.3d at 1583, and stating that "[r]esort to extrinsic evidence is appropriate *only when* an ambiguity remains after consulting the intrinsic evidence of record.") (emphasis added). "Such instances will rarely, if ever, occur." *Vitronics*, 90 F.3d at 1585. Moreover, extrinsic evidence cannot be used by the court to vary or contradict the terms of the claim. *Markman I*, 52 F.3d at 981; *see, e.g.*, *Storage Technology Corp.*, 329 F.3d at 832 (finding court improperly relied on extrinsic evidence in the form of an expert's declaration, especially because the court used the evidence to improperly limit a claim).

[18] The testimony of the inventor is not entitled to deference in properly construing the claims as the subjective opinion is irrelevant and any objective opinions are usually duplicative of evidence already available in the patent. *See Markman I*, 52 F.3d at 983, 985 ("testimony of [the inventor] and his patent attorney on the proper construction of claims is entitled to no deference" because subjective intent is not the issue); *see also* *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379 (Fed.Cir.2000); *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed.Cir.1997); *Roton Barrier, Inc. v. Stanley Works*, 79 F.3d 1112, 1126 (Fed.Cir.1996) ("We have previously stated that an inventor's 'after-the-fact testimony is of little weight compared to the clear import of the patent disclosure itself.' ") (quoting *North American Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1577 (Fed.Cir.1993)); *cf.* *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217-18 (Fed.Cir.1995) (relying upon extrinsic evidence of the inventor's own experimentation to construe a claim term with the word "about").

[19] [20] A court should not alter or change the public record through extrinsic evidence. *Vitronics Corp.*, 90 F.3d at 1583. Competitors of the patentee are entitled to rely on the public record of the patent. *Key Pharms.*, 161 F.3d at 716-17. Thus, extrinsic evidence may not be used to construe a claim at odds with the construction dictated by the patent's public record. *Id.* at 716 ("What is disapproved of is an attempt to use extrinsic evidence to arrive at a claim construction that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent."). Moreover, it is improper for the court to consider the patentee's commercial embodiment of the patent in determining claim meaning. *Glaxo Group Ltd. v. TorPharm, Inc.*, 153 F.3d 1366, 1373 (Fed.Cir.1998) (citing *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418 (Fed.Cir.1994)).

[21] In short, "[t]he [C]ourt may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the [C]ourt may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Momentum Golf, Inc. v. Concept Sports, Inc.*, 2002 WL 1285341, (S.D.Iowa) (quoting *Karlin Technology, Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971 (Fed.Cir.1999)); *see also* *Markman I*, 52 F.3d at 981 ("Extrinsic evidence is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims."). The court should treat opinion testimony on claim construction with the utmost caution. *Vitronics*, 90 F.3d at 1585. In addition, the court should discount expert testimony presented by an unqualified witness, *See Merck & Co.*, 347 F.3d at 1371 (finding the district court properly discounted the testimony of a witness who was a chemist but was not qualified in pharmacology as the witness was not qualified in the field of the invention), testimony that is inconsistent with the intrinsic evidence, *Vitronics*, 90 F.3d at 1584; *Bell & Howell Document Mgmt. Prods.*, 132 F.3d at 706, those portions of expert testimony that are conclusory

declarations devoid of supporting facts, *see* Zelinski, 185 F.3d at 1317 (finding district court properly characterized patent attorney expert's statement as conclusory because the statement was an assertion without further explanation), and testimony that is not necessary. *See* Trilogy Communications, Inc. v. Times Fiber Communications, Inc., 109 F.3d 739, 744 (Fed.Cir.1997) (upholding exclusion of expert testimony as "not necessary and certainly not crucial" where "the district court has concluded that the patent specification and the prosecution history adequately elucidate the proper meaning of the claims").

Based on the foregoing, the Court considers extrinsic evidence for the purpose of understanding the technology behind Kemin's patents. However, because the intrinsic evidence resolves any ambiguities in the claim terms, the Court does not rely on this evidence for claim interpretation. The Court finds it unnecessary to strike offending extrinsic evidence from the record; however, the Court disavows any reliance on such evidence in the following construction of the claims in issue. *See, e.g.*, Pitney Bowes, 182 F.3d at 1309; Markman I, 52 F.3d at 983 (finding that, at least as to expert opinions that are merely legal opinions, "the court has complete discretion to adopt the expert legal opinion as its own, to find guidance from it, or to ignore it entirely, or even to exclude it.").

The Court finds it inappropriate to give any weight to the deposition testimony of Dr. Khachick, the inventor of the '714 patent. Furthermore, the testimony presented in the *Markman* hearing by Dr. Ronald A. Daignault and Dr. Christopher Nelson was of limited use. Dr. Daignault's testimony, as a patent attorney and scientist, was fraught with legal conclusions as to the correct interpretation of the patent claim, which is wholly improper, and coupled with his lack of any lab time since the late 1960's, his testimony adds little to how a person of ordinary skill in the art would understand the claims in issue during the relevant time period, other than to the extent his testimony essentially conceded certain of such issues.FN5 Dr. Nelson's testimony did assist the Court with background on the technology, but his testimony as to how a person skilled in the art would understand the claims must be tempered with due regard for his interest in the subject matter of the action. At bottom, the Court assigns little weight to the substance of the expert testimony.

FN5. During the *Markman* hearing, counsel for Kemin moved to exclude the testimony of Dr. Daignault. Upon review of the entire record the Court denies the motion. The Court finds the evidence was admissible, though of limited weight on issues other than points of essential agreement. Dr. Daignault was more an advocate than an evidentiary resource.

## **E. The Claim Terms In Issue**

Kemin contends that the purified lutein products offered for sale in the U.S. by PIVEG infringe, at the least, claims 1, 2, and 4 of the '714 patent. Specifically, with respect to claim 1, Kemin contends PIVEG's purified lutein product contains substantially pure lutein crystals derived from lutein-containing plant extracts as evidenced by a preliminary chemical analysis and PIVEG's own marketing materials.FN6 In addition, Kemin further alleges infringement of claims 1 and 2 of the ' 564 patent. Kemin contends that discovery will show the lutein purification process employed by PIVEG at its plant located in Celaya, Mexico infringes on the ' 564 patent as indicated by the presence of residual propylene glycol in PIVEG's purified lutein product.FN7 Whether infringement has occurred and continues to occur depends in part on the interpretation of the patent's claims.FN8

FN6. Kemin contends a preliminary chemical analysis of PIVEG's purified lutein product indicates that

92.63% of the carotenoids present are free-form, lutein crystals. Kemin further alleges that PIVEG's marketing materials indicate its product contains 87% (plus-or-minus sign) 2% lutein and a certificate of analysis provided by PIVEG indicates lutein purity of 90.204%.

FN7. Kemin contends a preliminary chemical analysis of PIVEG's purified lutein product revealed the presence of residual propylene glycol, indicating the use of this in its process. Kemin further alleges chemical analysis shows the level of purification achieved by PIVEG (92.63% on average) is nearly identical to that achieved by Kemin (92.45%) using the patented process.

FN8. For example, as will be discussed in more detail, one of the main contentions between the parties is the level of purity of the lutein the '714 patent protects. Kemin contends the '714 patent protects carotenoid compositions with lutein concentrations of about 90% or higher. Meanwhile, PIVEG contends the patent requires lutein concentrations of 97% or higher.

## **1. Construction of the '714 Patent Claims**

Kemin alleges PIVEG has infringed Claims 1, 2, and 4 of the '714 patent. The Court relies solely on the claim and the specification in defining its construction of the claims in the '714 patent. The Court does not rely on any prosecution history as there were no amendments made to the patent application during its prosecution and it is too sparse to aid in interpreting the claims. In addition, the Court did consider extrinsic evidence in order to understand the underlying technology and to ensure that the Court's interpretation is consistent with how a person of ordinary skill in the art would interpret the claims.

### **a. Construction of Claim 1**

Kemin's lawsuit alleges infringement of claim 1 of the '714 patent by PIVEG. It is the construction of this claim that is most contested by the parties, and their respective proposed constructions are vastly different. Claim 1 of the '714 patent reads:

The carotenoid composition consisting essentially of substantially pure lutein crystals derived from plant extracts that contain lutein, said lutein crystals being of the formula: (chemical compound formula given), wherein the lutein is substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract.

Going first to the language of the claim, the Court finds that one of ordinary skill in the art would understand the plain meaning of claim 1 of the '714 patent to describe a carotenoid composition derived from plant extracts that contain substantially pure lutein. Moreover, the plain meaning of the claim indicates that the lutein crystals would have the recited structural formula.

[22] The Court also finds that claim 1 of the '714 patent is a claim to a composition, contrary to PIVEG's suggestion that the composition claims of the '714 patent are product-by-process claims. The claim does not use language that limits the composition to being a product-by-process. In other words, the composition and the process are separate, independent claims. FN9 *See Amgen Inc.*, 314 F.3d at 1326 (quoting *SRI Int'l*, 775 F.2d at 1122). PIVEG repeatedly points out that the '714 patent is directed to a carotenoid composition derived from plant extracts as a result of the process in claims 5-20 of the '714 patent. In contrast,

according to Kemin, there are two basic methods to obtain substantially pure lutein, the process described in the ' 714 patent and that described in the ' 564 patent. Kemin prosecutes its action for alleged infringement of the ' 564 patent based on the results of a preliminary chemical analysis that points to infringement of the ' 564 patent process, and not the process protected by the '714 process. The Court finds that the composition claim in claim 1 is not limited by or tied to the process claims of the ' 714 patent, but is separate and independent.

FN9. "There is a rebuttable presumption that different claims are of different scope." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1326 (Fed.Cir.2003). PIVEG has presented no evidence to rebut the presumption that claim 1's product composition is linked in scope to claim 5's process.

The primary issue for the Court to resolve, and the issue of the most disagreement between the parties, is the meaning of "substantially pure lutein." The Court will first define "substantially" and then construe the meaning of the phrase "substantially pure lutein." As part of this process, the Court will look at whether a numerical range is incorporated by the claim, and what method of measurement is to be used to determine purity.

#### **i. "Substantially Pure Lutein"**

[23] Federal Circuit decisions discussing the definition of the term "substantially" are instructive. In a recent decision, *Deering Precision Instruments, L.L.C. v. Vector Distribution Systems, Inc.*, the court was required to construe the meaning of the term "substantially" in a patent claim. *Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1322 (Fed.Cir.2003); *see also* *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1030-31 (Fed.Cir.2002) (construing the term "substantially"); *Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc.*, 206 F.3d 1408, 1414-15, 1418 (Fed.Cir.2000) (same); *York Prods., Inc. v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1572-73 (Fed.Cir.1996) (same). The court recognized that reference to the dictionary and prior cases show the term "substantially" is capable of multiple interpretations. *Deering Precision Instruments, L.L.C.*, 347 F.3d at 1322-23.

As the *Deering* court noted, "substantially" has "a dual ordinary meaning ... as connoting a term of approximation or a term of magnitude." *Id.* at 1323; *see also* *Epcon Gas Sys., Inc.*, 279 F.3d at 1031. The court found it was proper to look to the specification to determine whether the term "substantially" is a term of magnitude or a term of approximation. *Deering Precision Instruments, L.L.C.*, 347 F.3d at 1323. In *Deering*, the court went to the specification and found the term "substantially" from the phrase "substantially in the plane" was a term of magnitude. *Id.* The court then construed "substantially" to require a "not insubstantial" portion. *Id.* at 1324. The term "substantially" in the phrase "substantially pure lutein" as set forth in the '714 patent is a term of magnitude. This Court likewise construes "substantially" to require a not insubstantial portion of the carotenoid composition be lutein for it to be considered "substantially pure."

PIVEG focuses on the phrases "substantially pure lutein crystals," "substantially free from other carotenoids," and "substantially free from chemical impurities found in the natural form of lutein in the plant extract" as the terms in issue.FN10 PIVEG argues that the three phrases, "lutein crystals," "other carotenoids," and "chemical impurities found in the natural form of lutein in the plant extract," were chosen by the inventor, who then used modifiers to describe the boundaries of the invention. The modifiers used are "substantially pure" and "substantially free from." PIVEG asserts that the word "substantially" has the ordinary and common meaning of "being largely but not wholly that which is specified" as evidenced by the

definition found in the Merriam-Webster dictionary.

FN10. In interpreting claim 1 of the '714 patent, PIVEG contends that:

one of ordinary skill in the art would understand that "substantially pure lutein crystals" means the carotenoid composition *as a whole* usually contains more than 90% lutein as measured by UV/visible spectrophotometry, and most often contains greater than 97% lutein as measured by UV/visible spectrophotometry; "substantially free from other carotenoids" means that, as a percentage of *all the carotenoids in the composition*, lutein must constitute at least 97.82% of all the carotenoids (i.e., the measure of other carotenoids cannot be more than 2.18%), since the carotenoid profile within the composition is described in the patent specification as 97.82% lutein by HPLC; "substantially free from chemical impurities found in the natural form of lutein in the plant extract" means that chemical impurities such as anthocyanins, plant sterols, and other materials found naturally in the plant extract have been removed at least to the extent that they are not detectable by NMR measurements. "Substantially free from chemical impurities found in the natural form of lutein in the plant extract" does not address chemical residues from any other sources, including those that may remain from the reagents used in the process to extract, saponify, or recrystallize the lutein, and does not limit the presence or absence of chemical residues from other sources in any way.

PIVEG maintains this is the interpretation required by the plain meaning of the claim language and further supported by the patent specification.

Meanwhile, Kemin argues the phrase "substantially pure lutein" relates to the carotenoid composition, and the additional phrases are not to be considered separately, but rather all relate to the level of lutein purity in the carotenoid composition. Moreover, the same methods of analysis are used to make the determination as to whether "substantially pure lutein crystals" are "substantially free from other carotenoids" and "substantially free from chemical impurities found in the natural form of lutein in the plant extract."

The Court finds PIVEG's proposed construction is inconsistent with the language of the claim itself. 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.

## ii. Numerical percentage

The next issue concerns whether a certain numerical percentage is required to be considered "substantially pure lutein," and if so, quantifying the required percentage. Kemin asserts that the construction of the term "substantially pure" should not be limited to a strict numerical boundary. Kemin argues the Federal Circuit has recognized that "like the term 'about,' the term 'substantially' is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter.'" *Ecolab Inc.*, 264 F.3d at 1367 (quoting *Pall Corp.*, 66 F.3d at 1217). Accordingly, Kemin urges the Court to not construe the term

"substantially pure" in claim 1 as limited to a strict numerical boundary.

[24] [25] "It is usually incorrect to read numerical precision into a claim from which it is absent...." *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1551 (Fed.Cir.1996) (discussing meaning of "relatively small"). "Thus, when a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims." *Renishaw*, 158 F.3d at 1249; *see also* *Modine Mfg. Co.*, 75 F.3d at 1551 ("Ordinarily a claim element that is claimed in general descriptive words, when a numerical range appears in the specification and in other claims, is not limited to the numbers in the specification or other claims.") (citing *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed.Cir.1988) ("particular embodiments appearing in the specification will not generally be read into the claims")). In addition, the preferred embodiment in the specification cannot serve to limit the ordinary meaning of a claim term. *CCS Fitness, Inc.*, 288 F.3d at 1366 (finding a patentee need not describe every possible future embodiment).

The Court notes, however, that prior art compositions such as those used in the poultry industry and acknowledged in the patent achieved 70% purity by UV/visible spectrophotometry. ('714 patent, col. 2, lns. 51-54; col. 4, lns. 43-49). In the written description of the patent, the inventor provides examples of his composition to distinguish his composition from the prior art compositions with 70% purity used in the poultry industry. This is indicative as to what is meant by "substantially" in the '714 patent, and more precisely, the levels of purity required. Because 70% purity was considered "substantially pure" at the time of the '714 patent, and the '714 patent is premised on a composition of far greater purity, the Court finds a numerical boundary is necessary and proper when the claim and the specification are considered together. In other words, there needs to be some quantification of the phrase "substantially pure" as it relates to the level of lutein purity in the carotenoid composition.

Kemin argues that if a numerical boundary is to be set, the Court should construe the claim to require 90% purity. Kemin argues this is the interpretation supported by the specification as the claim does not indicate a specific numerical percentage to define "substantially pure." Specifically, Kemin points to the portion of the specification that indicates the purified lutein "exists in substantially purer form in comparison with lutein found in the matrix of any naturally occurring plant." ('714 patent at col. 5, lns. 30-33). In addition, the specification states the purity of the resulting lutein within the carotenoid composition is "usually greater than 90%." ('714 patent at col. 5, lns. 17-18). Kemin explains this statement to mean that "about 90% of the carotenoids present in the plant extract would be lutein crystals based on quantitative HPLC analysis of the carotenoid composition." Kemin also asserts that a person of ordinary skill in the art "would understand that in addition to the carotenoid composition, the plant extract would also contain certain residual plant material, such as waxes, and certain fatty acids, which could be quantified by UV/visible spectrophotometry."

PIVEG contends that a separate numerical percentage is warranted for each of the three individual phrases it posits the claim contains. Briefly, PIVEG maintains that:

one of ordinary skill in the art would understand that this patent discloses a carotenoid composition ... consisting essentially of "substantially pure lutein crystals," i.e., crystals consisting of usually greater than 90% lutein by UV/spectrophotometry; is "substantially free from other carotenoids," meaning that lutein consists at least 97.82% of the carotenoids present leaving 2.18% for other carotenoids"; and is "substantially free from chemical impurities found in the natural form of lutein in the plant extract," meaning that these chemical impurities are not detectable by NMR imaging.

The Court has already determined the three phrases urged as separate and distinct by PIVEG are not to be interpreted separately. Rather, the phrase "substantially pure" refers to the lutein purity in the carotenoid composition. Thus, separate numerical percentages for the phrases "substantially pure lutein crystals," "substantially free from other carotenoids," and "substantially free from chemical impurities found in the natural form of lutein in the plant extract" are not warranted.

Therefore, PIVEG asserts in the alternative that the claim terms "substantially pure lutein crystals" means "the carotenoid composition as a whole usually contains more than 90% lutein as measured by UV/spectrophotometry, ... most often 97%." To support its construction, PIVEG points out in the specification that the patent states "further purification of this [70% pure lutein] composition may be employed to produce lutein with purity greater than 97% ...." ('714 patent, col. 4, lns. 50-52). After describing the method used to further purify the lutein, the specification describes the resulting lutein purity as "usually greater than 90%, most often greater than 97% as determined by UV/visible spectrophotometry." ('714 patent, col. 5, lns. 17-19). The specification further describes the carotenoid composition in terms of HPLC analysis that "consists of 94.79% lutein, 3.03% of its geometric isomers, and a total of 2.18% of other measurable carotenoids." ('714 patent, col. 5, lns. 21, 22).

" 'Although 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 Communications, Inc., 156 F.3d at 1187 (quoting *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed.Cir.1988)); *see also* *Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed.Cir.1986). In fact, "when a claim term is expressed in general descriptive words, [the court] will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims." *Renishaw*, 158 F.3d at 1249; *see also* *Modine Mfg. Co.*, 75 F.3d at 1551. Kemin argues PIVEG's reference to the specification to determine specific percentages required by the '714 patent is inconsistent with case law in that it serves to read a limitation into the claim that does not appear in the actual language of the claim.

Based on the claim language and the definition of "substantially" discussed above, along with the written description of the patent and the examples found in the specification, the Court construes the phrase "substantially pure" to require at least 90% purity. Clearly the patent only covers lutein with a purity level greater than at least 70%, as this is covered by prior art. Further, the specification makes clear that the lutein achieved by the patent inventor was usually in excess of 90%, and the Court finds that a person of ordinary skill in the art would read the claim and the specification as covering lutein with a purity level of at least 90% as compared to the carotenoid composition.

In addition, the Court finds the scope of the patent extends to lutein that is suitable for human consumption. The Court previously discussed this potential construction of the scope of claim 1 of the '714 patent in its order on the plaintiff's motion for preliminary injunction. In that order, the Court found the term "substantially pure lutein" covers lutein that is suitable for human consumption. One of the basic and novel properties of the '714 invention is that the purified lutein crystals are suitable for human consumption. The specification supports this construction. The further record made subsequent to the preliminary injunction application has not convinced the Court to the contrary.

The specification indicates that, prior to the '714 patent, "pure lutein suitable for human use has not been commercially available," and "[p]ure lutein, free from chemical contaminants and suitable for human

consumption is needed" for use in human intervention studies and as a color additive. ('714 patent, col. 2, lns. 5-10; col. 2, lns. 51-60). One of the objectives of the '714 patent was to fulfill this need by providing pure lutein suitable for human consumption for use in cancer prevention trials and treatment and as a food additive. ('714 patent, col. 3, lns. 17-24). The examples from the specification further delineate the objective that the pure lutein be suitable for human consumption by providing for use of materials that are "food grade" by meeting the "qualifications for food ingredients," ('714 patent, col. 5, lns. 50-53 (marigold flowers tested "to ensure they meet qualifications for food ingredients"); col. 5, lns. 54-56 (use of "food grade aqueous potassium hydroxide"); col. 5, ln 61 (use of "food grade" ethanol)), and discussing the preparation of lutein for oral supplementation ('714 patent, col. 8, lns. 3-61).

Claim 1 uses the transition phrase "consisting essentially of," which serves to exclude elements that are not specifically listed in the claim that would materially alter the novel and basic properties of the lutein. *See, e.g., PPG Indus., Inc. v. Guardian Indus., Corp.*, 156 F.3d 1351, 1354 (Fed.Cir.1998). Thus, the language of the claim specifically excludes anything that would make the resulting purified lutein crystals unsuitable for human consumption.

With regard to whether lutein is "substantially pure" so as to be suitable for human consumption, the Court notes that the Federal Circuit has found "it is quite sensible to look to the FDA to determine what amounts are considered pharmaceutically effective." *Key Pharms*, 161 F.3d at 718. Likewise, this Court finds a person skilled in the art would know to look to the FDA standards governing whether a product such as lutein is suitable for human consumption.

### **iii. Method of measurement**

UV/visible spectrophotometry does not distinguish between different carotenoids present and therefore cannot make absolute measurements as to the amount of lutein present. However, this measurement in conjunction with HPLC analysis can render a specific, quantitative measurement of lutein purity for purposes of the '714 patent. The Court therefore finds, and the parties agree, that both UV/visible spectrophotometry and HPLC are required to accurately measure lutein purity. The Court finds the evidence is undisputed a person of ordinary skill in the art at all material times would recognize UV/visible spectrophotometry in conjunction with HPLC is the correct method of measurement to determine lutein purity, and therefore must necessarily be considered the proper method of measurement for purposes of the '714 patent.

### **iv. Construction of Claim 1**

Based on the foregoing, the Court's construction of claim 1 of the '714 patent, is 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.

### **b. Construction of Claim 2**

Kemin's lawsuit also alleges infringement of claim 2 of the '714 patent by PIVEG. Claim 2 of the '714 patent reads:

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.

In interpreting claim 2 of the '714 patent, Kemin states:

One of ordinary skill in the art would understand the plain meaning of claim 2 of the '714 patent which states the plant extract of claim 1 of the '714 patent is derived from naturally occurring plants selected from the group consisting [of] fruits, vegetables, and marigolds. Moreover, because claim 2 depends from claim 1, claim 2 incorporates all of the limitations of claim 1 and adds the further limitations described above.

PIVEG does not dispute this interpretation of claim 2 of the '714 patent and the Court, upon review of the intrinsic evidence, finds this is an accurate interpretation of the claim. Thus, the Court construes claim 2 of the '714 patent as described above.

### **c. Construction of Claim 4**

Kemin's lawsuit also alleges infringement of claim 4 of the '714 patent by PIVEG. Claim 4 of the '714 patent reads:

The lutein carotenoid composition of claim 1 wherein the lutein is derived from marigold flower extract.

In interpreting claim 4 of the '714 patent, Kemin states:

One of ordinary skill in the art would understand the plain meaning of claim [4] of the '714 patent which states that the lutein of claim 1 of the '714 patent is derived from marigold flower extract. Moreover, because claim 4 depends from claim 1, claim 4 incorporates all of the limitations of claim 1 and adds the further limitations described above.

PIVEG does not dispute this interpretation of claim 4 of the '714 patent and the Court, upon review of the intrinsic evidence, finds this is an accurate interpretation of the claim. Thus, the Court construes claim 4 of the '714 patent as described above.

## **2. Construction of the '564 Patent Claims**

Kemin alleges PIVEG has infringed Claims 1 and 24 of the '564 patent. The Court relies on the intrinsic evidence provided by the claim, the specification, and the prosecution history of the '564 patent in arriving at its construction of the asserted claims in this patent. In addition, the Court did use extrinsic evidence to understand the underlying technology and to ensure that the Court's interpretation is consistent with how a person of ordinary skill in the art would interpret the claims.

### **a. Construction of Claim 1**

Kemin alleges that the entire process detailed in Claim 1 of the '564 patent has been infringed by PIVEG. Claim 1 of the '564 patent reads:

A process for producing xanthophyll crystals from a xanthophyll diester-containing plant oleoresin that comprises the steps of:

- a) admixing the oleoresin with propylene glycol with heating to a temperature of about 50 degree C. to about 60 degree C. to form a homogeneous liquid;
- b) admixing an aqueous alkali solution of sodium or potassium hydroxide with said homogeneous liquid to form a saponification reaction mixture that consists essentially of about 35 to about 50 weight percent oleoresin, about 30 to about 45 weight percent propylene glycol, about 5 to about 10 weight percent alkali as potassium hydroxide and about 7 to about 15 weight percent water as initially admixed components, wherein the total weight of said oleoresin plus propylene glycol constitute at least 75 weight percent of said reaction mixture;
- c) maintaining said saponification reaction mixture at a temperature of about 65 degree C. to about 80 degree C. for a time period sufficient to saponify the xanthophyll diester and form a saponified reaction mixture containing xanthophyll crystals;
- d) admixing about 3 to about 19 volumes of water at a temperature of about 60 degree C. to about 80 degree C. per volume of saponified reaction mixture to form a diluted reaction mixture containing xanthophyll crystals;
- e) gently admixing said diluted reaction mixture until homogeneous;
- f) collecting the xanthophyll crystals from said diluted reaction mixture; and
- g) washing and then drying the collected xanthophyll crystals.

[26] Claim 1 of the '564 patent is a process for saponifying and purifying xanthophyll crystals from plants. Infringement of a process patent occurs upon "unauthorized performance of substantially the same process steps in substantially the same way to accomplish substantially the same result." *Int'l Glass Co. v. United States*, 187 Ct.Cl. 376, 408 F.2d 395, 400 (Ct.Cl.1969). PIVEG states that "[t]he claim elements that require attention here are those that provide ratios of components in each step, temperature ranges, the time allotted for reactions during each step or stage of the process and, of course, the order of the steps." Of these elements, the only real issue is the order of the steps. The other elements are expressly and unambiguously stated in the claim language and supported by the specification and prosecution history. Two less significant issues the Court resolves, are (1) whether the claim excludes the use of substances other than propylene glycol, and (2) whether the claim requires the use of either sodium hydroxide or potassium hydroxide independently or whether they may be used in some combination.

#### **i. Order of the steps**

[27] [28] When determining whether a claim requires the steps of a process patent be sequential, the court needs to be wary of importing a limitation from the specification or the preferred embodiment into the claim. *See Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369 (Fed.Cir.2003). "Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one." *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1342-43 (Fed.Cir.2001) (citing cases to support this statement). The performance of the steps in the order written may be required, however, when the process implicitly requires they be performed in the stated order. *Id.* (citations omitted).

[29] To determine whether the claim requires that the steps be performed sequentially involves a two-part

test. *Altiris, Inc.*, 318 F.3d at 1369 (citing *Interactive Gift Express, Inc.*, 256 F.3d at 1343). First, the court looks to the language of the claim to determine if, as a matter of logic or grammar, the steps must be performed in the written order. *Id.* (citing *Interactive Gift Express, Inc.*, 256 F.3d at 1343); *see, e.g.*, *Loral Fairchild Corp. v. Sony Elecs. Corp.*, 181 F.3d 1313, 1321 (Fed.Cir.1999). If the claim language itself contains no such indication, the court looks to the specification to determine whether it requires, either directly or implicitly, that the steps be performed in order. *Altiris, Inc.*, 318 F.3d at 1369 (citing *Interactive Gift Express, Inc.*, 256 F.3d at 1343).

[30] In addition, the patent applicant may disclaim, renounce, or disavow claim scope during the prosecution of the patent. *See Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed.Cir.2003); *see also* *Digital Biometrics, Inc.*, 149 F.3d at 1347 ("The public has a right to rely on such definitive statements made during prosecution."). However, any surrender of scope or subject matter during the prosecution phase must be clearly and unambiguously expressed by the applicant. *Invitrogen Corp.*, 327 F.3d at 1368 (citing *Middleton, Inc. v. Minn. Mining & Mfg. Co.*, 311 F.3d 1384, 1388 (Fed.Cir.2002), and *Inverness Med. Switz. GmbH v. Princeton Biomeditech Corp.*, 309 F.3d 1365, 1372 (Fed.Cir.2002)).

In *Loral Fairchild Corp. v. Sony Electronics Corp.*, the court held the steps must be performed in the written order because the second step of the process called for the alignment of a second structure with a first structure *formed by the first step*. *See Loral Fairchild Corp.*, 181 F.3d at 1321. In *Mantech Environmental Corp. v. Hudson Environmental Services, Inc.*, the court held the steps in a method claim had to be performed in the sequential order as written because the subsequent steps each referenced something that logically indicated the prior step had been performed. *Mantech Envntl. Corp. v. Hudson Envntl. Servs., Inc.*, 152 F.3d 1368, 1375-76 (Fed.Cir.1998).

In *Altiris, Inc. v. Symantec Corp.*, however, the court found neither the language nor the written description, which discussed a preferred embodiment, required the steps be performed in the order written. *Altiris, Inc.*, 318 F.3d at 1370-71. In so finding, the court took into consideration extrinsic evidence where two experts testified that it was technologically possible to perform the steps in an order different from that written and still achieve the inventor's purpose. *Id.* at 1371. The expert testimony in this case served "the permissible purposes of aiding our understanding of the technology and in helping us view the patent through the eyes of the skilled artisan." *Id.* (citing *Pitney Bowes*, 182 F.3d at 1309).

[31] The term "comprising" is a term of art used in claim language and means the named elements are essential, but other elements may be added and still fall within the scope of the claim. *See Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1380 (Fed.Cir.2001) (finding it is a well-established principle that the mere addition of elements to a product or process will not negate infringement); *Vivid Technologies, Inc.*, 200 F.3d at 811 (recognizing that "comprising" is a signal which is "generally understood to signify that the claims do not exclude the presence in the accused apparatus or method of factors in addition to those explicitly recited"); *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (Fed.Cir.1991) (finding a claim "which uses the term 'comprising' is an 'open' claim which will be read on devices which add additional elements"); *see also* *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1271 (Fed.Cir.1986); *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482 (Fed.Cir.1984).

PIVEG argues that it is crucial for the steps in claim 1 to be performed in the exact order stated. In other words, steps a through g are to be sequentially performed in the order listed. PIVEG maintains that these seven steps are disclosed and arranged in such a way as to require that their order is unalterable. *Mantech Environmental Corp.*, 152 F.3d at 1376 ("the sequential nature of the claim steps is apparent from the plain

meaning of the claim language and nothing in the written description suggests otherwise."). PIVEG cites to the decision in *Mantech* and states it was based on the fact that subsequent steps referred to things provided by the previous step.

As PIVEG contends, the steps of claim 1 of the '564 patent are organized in a fashion to refer to measures and resulting materials provided by a previous step. For example, step a describes a process to form a homogenous liquid and step b provides for the mixing of an aqueous alkali solution with "said homogenous liquid." Therefore, PIVEG maintains that step a must be performed before step b. Likewise, step c refers to "said saponified reaction mixture," thereby putting it in order after step b. Thus, PIVEG argues that the sequential order of the steps is required based on the plain language of the claim. *See Invitrogen*, 327 F.3d at 1368 (concluding that steps were sequential in part through the claim's use of the term "said" in later steps).

In addition, PIVEG refers to the specification as evidence that the order of the steps in claim 1 is important. *See Altiris, Inc.*, 318 F.3d at 1369 (citing *Interactive Gift Express, Inc.*, 256 F.3d at 1342-43, and finding it proper to refer to the specification to determine whether it directly or implicitly requires sequential construction). PIVEG provides citation to examples from the specification that it contends indicate step a is before step b. ( *See* '564 patent, col. 4, lns. 41-47; col. 5, lns. 2-4, 47-48; col. 6., lns. 26-30).

PIVEG also refers to the Examiner's statement in the prosecution history as indicating the process requires the steps be performed in the order listed. The Examiner stated "[t]he claims are drawn to producing xanthophyll crystals which comprises the steps of admixing a plant oleoresin with propylene glycol *followed by* alkali treatment." Because Kemin did not file "Comments on Statement of Reasons for Allowance," PIVEG argues they acquiesced in the Examiner's rationale.FN11 Based on the foregoing, PIVEG argues the steps of the process must be completed in the order listed, specifically that the step of admixing oleoresin and propylene glycol must occur before treatment with aqueous alkali.

FN11. The examiner is allowed to set forth reasons for allowance if he or she feels the record of prosecution does not make those reasons clear. *See* 37 C.F.R. 1.104(e). The applicant is allowed to file his own comments on the reasons for allowance as filed by the examiner. *See id.* The statement of reasons for allowance along with the applicant's replies provide a record of the examiner's reasons for allowance. *See Zenith Labs., Inc.*, 19 F.3d at 1421, 1424.

Kemin asserts that, contrary to PIVEG's contentions, neither the language of the claim nor the specification require the performance of the steps of the process sequentially. Kemin argues that PIVEG violates a basic principle of claim construction by attempting to restrict the claim to the precise order of steps. Kemin maintains that the plain language of the claim and the specification do not mandate or require a specific order of performance for the steps of claim 1.FN12

FN12. Kemin asserts PIVEG's reliance on *Invitrogen Corp. v. Biocrest Manufacturing L.P.*, 327 F.3d 1364 (Fed.Cir.2003) for the proposition that "said" signifies "the product of a preceding step ... must occur first" is misplaced as the claim at issue in that case used the phrase "comprising the following steps *in order*," a phrase not present in claim 1 of the '564 patent at issue in this case. The Court agrees that *Invitrogen* is distinguishable.

To the contrary, Kemin argues the claim and the specification do not require successful completion of the prior step, particularly with respect to steps a and b. There is no indication that the propylene glycol of step a must necessarily be added before the addition of the aqueous alkali of step b. As further evidence of this, Kemin cites to the opinion of its expert, Dr. Carta, that despite being preferable, "the order of addition is not critical to the process."

Kemin also argues that PIVEG's reliance on the prosecution history of the '564 patent is misplaced. Kemin argues the rationale behind the Examiner's allowance was not directed to the order in which the plant oleoresin was mixed with the propylene glycol and the alkali treatment, but rather the use of the "propylene glycol treatment" itself. Kemin argues this is borne out by the Examiner's statements, and relied on by PIVEG, that "[t]he claims of the present application are specifically drawn to propylene glycol treatment" and allowing the application "in the absence of prior art teaching that would motivate one of ordinary skill in the art to use propylene glycol in producing xanthophyll crystals...." Based on the foregoing, Kemin urges the Court to reject PIVEG's assertions and instead find that "claim 1 of the '564 patent should not be construed to include a limitation requiring that the steps of the claimed process must be performed in the order recited."

[32] The Court finds that the order of the steps of the '564 patent process need not be performed sequentially as listed in claim 1. There is nothing in the claim language or the specification expressly requiring that the steps be performed in the exact order listed. The Court finds one of ordinary skill in the art would understand steps a and b of the process covered by the claim 1 could be performed in alternate sequences and still achieve the purpose of the patent, in this case, creating a product consisting of substantially pure lutein. *See Altiris, Inc.*, 318 F.3d at 1370-71. While recognizing that the language of the steps in claim 1 refer to previous steps, the Court finds on this record that one skilled in the art would understand steps a and b are interchangeable, similar to the addition of ingredients in a cooking recipe, with no discernible or important difference in the reaction or the end result.FN13 In addition, the process of claim 1 does not prohibit additional steps inserted into the process. By using the term "comprising," claim 1 of the '564 patent indicates other steps or elements can be present. *See Vivid Technologies, Inc.*, 200 F.3d at 811.

FN13. PIVEG did present expert testimony at the *Markman* hearing where the expert stated that there would be a different reaction were the steps to be performed in a n alternate order but was unsure what that different reaction would be. Kemin's experts all uniformly stated there would be no significant difference in the reactions if the steps were performed in a different order. The Court notes that PIVEG's expert is currently a patent attorney and has not conducted lab experiments for over thirty years. In any case, the Court used the testimonies and affidavits of the parties' experts for the sole purpose "of aiding [the Court's] understanding of the technology and in helping [the Court] view the patent through the eyes of the skilled artisan." *Altiris, Inc.*, 318 F.3d at 1371 (citing *Pitney Bowes*, 182 F.3d at 1309).

## **ii. Propylene glycol and use of other solvents**

[33] [34] [35] For infringement of a process invention, all of the claimed steps of the process must be performed. *See Applied Materials, Inc. v. Advanced Semiconductor Materials Amer., Inc.*, 98 F.3d 1563, 1574 (Fed.Cir.1996). As the Court previously noted, however, the language "comprises the steps of" means that the accused process may still infringe if it includes all of the steps in the patented process even while adding some additional steps. *See Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 832 (Fed.Cir.1991). This means that even if other substances are included in the composition, it will still fall within the claim's

scope if the other substance does not materially alter a basic and novel property of the invention. *See, e.g., Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1579-80 (Fed.Cir.1984). However, if the patented process requires a named element, the accused process avoids infringement if it uses an additional element, the use of which is excluded by the patent.

[36] PIVEG argues that claim 1 excludes the use of organic solvents. PIVEG points to the ratio of the constituents making up the "saponification reaction mixture," the use of propylene glycol to obtain the desired purity, and washing the crystals with water to show the use of organic solvents is excluded from the scope of the claim. PIVEG also argues that it was this aspect of the process that the inventors used to distinguish their process from prior art in stating "unlike previous methods that used saponified marigold oleoresin as a starting material to isolate lutein ... there was no need to crystallize lutein from the saponified marigold oleoresin by the addition of organic solvents." ('564 patent, col. 4, lns. 52-59). The starting material is important in that it allows the patented process to avoid the use of organic solvents. PIVEG interprets this to mean that "the claimed process achieves its disclosed objectives by starting with an oleoresin nearly free from organic solvents such that *the use of organic solvents is avoided.*"

Kemin contends that "PIVEG wrongly asserts that the process of claim 1 of the '564 patent 'excludes the addition of any organic solvents other than propylene glycol.'" Kemin maintains that a careful reading of the specification does not lead to this broad conclusion and that there is no express exclusion of such solvents.

The Court finds that the use of propylene glycol is an essential element of the process encompassed by claim 1. It was, in fact, affirmatively noted by the examiner in his statement allowing the patent. It was the use of propylene glycol that set the process in this claim apart from prior art and was crucial to the grant of the '564 patent. Therefore, the Court construes claim 1 to require the use of propylene glycol.

The claim does not cover a process that substitutes another solvent in its place. However, the Court finds the claim does not exclude the use of substances in addition to propylene glycol. There is no language in the claim, the specification, or the prosecution history that indicates this limitation is appropriate. Other solvents may be used in addition to, but not in place of, propylene glycol in the process covered by claim 1. Therefore, use of another substance in addition to propylene glycol is within the purview of the patent so long as it does not materially alter the process in the claim.

### **iii. Sodium hydroxide and/or potassium hydroxide**

[37] The language of claim 1 provides that an "aqueous solution of sodium or potassium hydroxide" may be used. ('564 patent, col. 9, lns. 1-2). As relating to this process, Kemin contends that a person of ordinary skill in the art would understand that, from a chemical perspective, "there is no significant difference between the use of sodium hydroxide and/or potassium hydroxide as the alkali for the saponification reaction." In other words, a process using a mixture of potassium hydroxide and sodium hydroxide would be equivalent to a process using either potassium hydroxide or sodium hydroxide alone as the alkali for the saponification reaction. Kemin points to the testimony of its expert, Dr. Carta, that a process that uses a mixture of potassium hydroxide and sodium hydroxide would be the same as using either of these alone.

PIVEG disagrees and argues that the use of sodium hydroxide and/or potassium hydroxide results in different reactions whether used separately or together. As a result, PIVEG argues that the use of a mixture of alkalis, one being sodium hydroxide, is not within the scope of this claim. PIVEG's position is that the

use of sodium hydroxide results in a faster saponification reaction but leaves hard soaps difficult to dissolve using the simple water washes contemplated by the patent. On the other hand, using only potassium hydroxide results in a much slower process but leaves soft soaps that are easily dissolved. PIVEG argues the patent does not contemplate combining the two for saponification and that such a combination would have a profound effect on the speed of the reaction and the process to wash or dissolve the soaps. This description of the different reactions is found in PIVEG's Response to Plaintiff's Brief on Claim Construction, but PIVEG has provided no reliable evidence that there is actually a different reaction, either as part of its appendix or in the *Markman* hearing.

The Court finds the language cited above would be understood by a person of ordinary skill in the art to allow for the use of either sodium hydroxide or potassium hydroxide. This is obvious by the plain language of the claim and use of either sodium potassium hydroxide is covered regardless of any possible differences in the reaction. The Court also finds that a person skilled in the art would understand that some combination of sodium and potassium hydroxide could be employed to achieve the same result. Thus, in construing claim 1 the Court finds that the scope of the process consists of the use of either sodium hydroxide or potassium hydroxide or some combination of both.

#### **iv. Construction of Claim 1**

Based on the foregoing, the Court's construction of claim 1 of the '564 patent is as follows: One of ordinary skill in the art would understand the plain meaning of claim 1 of the '564 patent, which describes a process for the production of xanthophyll crystals from a plant oleoresin containing xanthophyll diesters. A "xanthophyll crystal" is an oxygenated or alcoholic derivative of a hydrocarbon carotene (or carotenoid) compound in crystalline form, ('564 patent at col. 1, lns. 15-16), and a "xanthophyll diester-containing plant oleoresin" is an extract from plant matter that contains xanthophyll diesters. ('564 patent at col. 2, ln. 66, and col. 3, lns. 37-38, 51-52, and 60). The term "homogeneous liquid" means a solution, a fine dispersion or a colloidal suspension in the context of the '564 patent. ('564 patent at col. 5, ln. 15). In addition, a person of ordinary skill in the art would understand the term 'saponification' to mean the alkaline hydrolysis of a fatty acid ester resulting in the formation of an alcohol and a fatty acid salt, ('564 patent at col. 5, lns. 44-47), a salient feature of which is that the formation of the xanthophyll crystals occurs directly via the saponification reaction and that no additional solvents are needed. ('564 patent at col. 4, lns. 45-52).

Based on the understanding of these terms, one of ordinary skill in the art would understand the process described in claim 1 of the '564 patent to comprise the following steps: "The saponification mixture is prepared by mixing the plant oleoresin with propylene glycol and an aqueous alkali solution of sodium or potassium hydroxide, collectively forming a fine dispersion(steps a and b)." ('564 patent at col. 5, lns. 13-15, and col. 7, lns. 23-35). The saponification mixture contains 35-40% oleoresin, 30-45% propylene glycol, 5-10% alkali, and 7-15% water. The saponification mixture is maintained at a temperature ranging from about 60 to 80C. This serves to saponify the xanthophyll diesters and form xanthophyll crystals (step c). ('564 patent at col. 5, lns. 13-36). Thereafter, approximately 3-19 volumes of water (per unit volume of the saponification mixture) are added at a temperature between about 60 and 80C and mixed to form a diluted mixture containing xanthophyll crystals (steps d and e). ('564 patent at col. 5, lns. 52-61). Finally, the xanthophyll crystals are collected from the diluted mixture (step f). ('564 patent at col. 6, lns. 6-21). These are then washed and dried (step g). ('564 patent at col. 6, lns. 22-32). The "saponification reaction mixture" consists of four constituents at specified weight percentages in a ratio of about 4:4:1:1. The weight percentage of oleoresin and propylene glycol should together make up about 75 percent of the "saponification reaction mixture."

The Court also finds steps a and b need not be performed sequentially, as one of ordinary skill in the art would have understood these steps could be performed in a modified order and still achieve the same final result. The scope of the claim also covers processes that consist of all the listed steps along with other additional steps as long as the additional steps do not meaningfully change the process described in the claim. In addition, while the use of propylene glycol is necessary and cannot be substituted for, the claim does not exclude the use of any and all additional solvents as part of the process. The Court also construes the claim as allowing for the use of either sodium hydroxide or potassium hydroxide or some combination of both.

## **b. Construction of Claim 2**

Kemin's lawsuit also alleges infringement of claim 2 of the '564 patent by PIVEG. Claim 2 of the '564 patent reads:

The process of claim 1 wherein the plant oleoresin is from marigold flowers (*Tagetes sp.*) And the xanthophyll is lutein.

In interpreting Claim 2 of the '564 patent, Kemin states:

One of ordinary skill in the art would understand the plain meaning of claim 2 of the '564 patent which states that claim 2 is the process of claim 1 wherein the oleoresin is extracted from marigold flowers and the xanthophyll is lutein. In addition, one of ordinary skill in the art would understand that the term xanthophyll is sometimes used generically to indicate any of several carotenoid alcohols such as lutein and zeaxanthin. Moreover, because claim 2 depends from claim 1, claim 2 incorporates all of the limitations of claim 1 and adds the further limitations described above. Thus, the dependant claim 2 further qualifies claim 1 by specifying that the xanthophyll is lutein.

PIVEG does not dispute this interpretation of claim 2 of the '564 patent and the Court, upon review of the intrinsic evidence, finds this is an accurate interpretation of the claim. Thus, the Court construes claim 2 of the '564 patent as described above.

## **Conclusion**

The Court has construed the claims in issue of the '714 patent and the '564 patent according to the principles delineated by the Federal Circuit. In so doing, the Court turned first to the intrinsic evidence, and then to the extrinsic evidence to aid in understanding and to ensure consistency, in interpreting the patents in issue. The Court hereby construes claims 1, 2, and 4 of the '714 patent and claims 1 and 2 of the '564 patent as detailed herein.

**IT IS SO ORDERED.**

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