IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

KEMIN FOODS, L.C., THE CATHOLIC UNIVERSITY OF AMERICA, Plaintiffs, vs. PIGMENTOS VEGETALES DEL CENTRO S.A. DE C.V., Defendant.	**No. 4:02-cv-40327** **ORDER ON PRELIMINARY INJUNCTION**

This matter is before the Court on Motion by Plaintiffs, Kemin Foods, L.C., and The Catholic University of America, for Preliminary Injunction (Clerk's No. 2). By way of this motion, Plaintiffs ask this Court to prevent Defendant from continuing to make, use, import, or sell its purified lutein crystals from plant extracts protected by U. S. Patent No. 5,382,714 ("the '714 patent"); and from practicing the process of extraction protected by U.S. Patent No. 5,648,564 ("the '564 patent"), and importing the product thereof into the United States of America, during the pendency of this lawsuit. For the reasons stated herein, the Motion for Preliminary Injunction with respect to the '714 patent is granted; the Motion for Preliminary Injunction with respect to the '564 patent is denied.

SUMMARY OF APPLICABLE FACTS

This case involves claimed patent protections for purified lutein crystals and the process for creating that material. During the late 1980's and early 1990's,

(non-PVDC or Kemin) research scientists began discovering in cancer research that anti-oxidants could be beneficial to human health. Lutein is recognized as having anti-oxidant properties. 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.

Kemin Foods, L.C., is an Iowa limited liability company with its principal office in Des Moines, Iowa. Kemin produces only one product, purified lutein crystals, a product protected by the '714 patent. Kemin acquired the rights to the '714 patent through its affiliate company, Kemin Industries, Inc., and The Catholic University of America. The Catholic University of America is a District of Columbia non-profit corporation with its principal office in Washington, D.C. In this order, these parties are collectively referred to as "Kemin" or "Plaintiffs".

Kemin produces the purified lutein crystals protected by the '714 patent using an extraction process protected by the '564 patent. Kemin produces and/or distributes purified lutein crystals in oils, powders, and in beadlet form. There are other companies who do sell "lutein" products, but Kemin points out these other products in the market labeling themselves as "lutein" are not purified free-form lutein crystals (as protected by the '714 patent), but really naturally occurring lutein esters, comprised of a different chemical compound altogether, and are, therefore, a non-infringing compound or product. Additionally, Kemin points out these other products do not provide

the advantages recently associated with Kemin's purified free-form lutein crystals and do not infringe patent '714.

Pigmentos Vegetales Del Centro ("PVDC") is a Mexican company primarily located in Celaya, Mexico. Historically, the primary business objective of PVDC was the manufacture of pigments for the poultry industry. Since 1978, PVDC has marketed lutein for use primarily in the poultry industry.

PVDC began creating and providing "poultry-grade" lutein, which has been 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/ skin, qualities desirable to the consumer. Based on the beneficial discoveries of lutein in eyeball and cancer research, in the early 1990's, PVDC developed its own process for obtaining and purifying lutein suitable for human consumption, the process allegedly being an extension of the process PVDC had been previously using to produce lutein for poultry feed additives.

Recently, PVDC began marketing powders, beadlets, and oils containing purified lutein crystals within the United States. Once becoming aware of PVDC's products, Kemin obtained samples and subjected the PVDC products to chemical testing. These tests revealed that PVDC's products contained the identical chemical compound of purified lutein crystals protected by patent '714. Additional chemical analysis conducted by Kemin further demonstrated that PVDC's products also contain propylene glycol. Accordingly, Kemin alleges PVDC's products infringe patent '714, and the

presence of propylene glycol indicates infringement of the ‘564 patent. Based on its beliefs, on July 9, 2002, Kemin filed suit against PVDC and contemporaneously filed this Motion for Preliminary Injunction.

Ultimately, PVDC answers Kemin’s infringement allegations by saying patent ‘564 is not valid, or is unenforceable; that PVDC 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 Patent and Trade Office (herein-after “PTO”) to make the necessary determinations regarding whether a patent should issue); and alternatively, that PVDC does not infringe the ‘714 patent. PVDC has also filed four counterclaims against Kemin. First, PVDC seeks a declaratory judgment that the ‘714 patent is invalid, or unenforceable, and that PVDC is not infringing patent ‘714; second, PVDC seeks a declaratory judgment that the ‘564 patent is invalid, or unenforceable, and that PVDC is not infringing patent ‘564; third, that Kemin has engaged in unfair competition; and fourth, due to the fraudulent procurement of the ‘714 patent, coupled with Kemin enforcing its exclusionary rights under the ‘714 patent, Kemin has violated the Sherman Act by exercising its fraudulently obtained monopolistic powers against legitimate competitors such as PVDC, and has committed anti-trust violations.

The Patents At Issue:

A) <u>'714 patent</u>

The '714 patent, issued on January 17, 1995, 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, Brussels sprouts, broccoli, green beans, and green peas) contain lutein. Lutein has also been discovered to exist in the flower petals of marigolds. Kemin alleges that the recently discovered benefits of using lutein arise only from using free-form lutein, as opposed to using lutein esters or oleoresins.

Kemin alleges the following claims of the '714 patent are infringed by PVDC:

Claim 1 of the '714 patent, which 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.

Claim 2 of the '714 patent, which 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.

Claim 4 of the '714 patent, which reads:

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

B) <u>'564 patent</u>

The '564 patent was issued on July 15, 1997. The '564 patent protects the process Kemin uses in producing the purified lutein crystals protected by the '714 patent. Specifically, purified xanthophylls (a yellow carotenoid pigment such as lutein) are extracted through an extraction process that does not use harmful organic solvents. The resulting lutein product does not exceed safe toxicity levels for human consumption. Up until the issuance of the '564 patent, while purified lutein crystals could be produced from plant extracts, such methods were not cost efficient and used potentially harmful organic solvents, resulting in a purified lutein crystal product containing some residue of potentially harmful organic solvents. These lutein crystals were not suitable for human consumption due to the presence of organic solvent residue.

The process protected by the '564 patent uses non-harmful propylene glycol and water extraction, resulting in lutein crystals without residue of potentially harmful organic solvents, and therefore the extracted lutein is suitable for human consumption. Kemin's purified lutein crystals, obtained under the '564 process, have now achieved the status of "Generally Recognized As Safe" under the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. §§ 301-397.

Kemin alleges that the whole process protected by the '564 patent is infringed by PVDC:

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:
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> 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 tie 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;
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> e) gently admixing said diluted reaction mixture until homogeneous;
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> f) collecting the xanthophyll crystals from said diluted reaction mixture; and

g) washing and then drying the collected xanthophyll crystals.

In the context of preliminary injunction applications, "the findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits". University of Texas v. Camenisch, 451 U.S. 390, 395 (1981). Thus, the findings of fact as well as any conclusions of law made during the course of determining this preliminary injunction are not to be considered final. See, Circle R, Inc. v. Smithco Mfg., Inc., 919 F. Supp. 1272, 1289 (N.D. Iowa 1996).

PRELIMINARY INJUNCTION STANDARD

Kemin's preliminary injunction motion is made pursuant to Fed. R. Civ. P. 65. Injunctions are authorized by the patent statute to protect against violation of a right secured by patent. 35 U.S.C. § 283. The Court of Appeals for the Federal Circuit has explained that Federal Circuit law, rather than regional circuit law, governs the issuance of an injunction pursuant to § 283. Hybritech Inc. v. Abbot Labs., 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1988). We use Federal Circuit law because issuing an injunction pursuant to section 283 enjoins "'the violation of any right secured by a patent, on such terms as the court deems reasonable,' [and so] a preliminary injunction of this type, although a procedural matter, involves substantive matters unique to patent law and, therefore, is governed by the law of [the Federal Circuit]". Id. at 1451; see also Circle R, Inc., 919 F. Supp. at 1272 (considering Federal Circuit law in a patent preliminary injunction case). The Federal Circuit Court of Appeals in Hybritech Inc. pointed out,

however, that purely procedural questions involving the grant of a preliminary injunction are controlled by the law of the appropriate regional circuit. Id. (recognizing that the Federal Circuit looks to the law of the appropriate regional circuit when reviewing whether a district court, in granting a preliminary injunction, violated Rule 65 of the Federal Rules of Civil Procedure, i.e., in the Eighth Circuit, Dataphase Sys. Inc. v. CL Sys., Inc., 640 F.2d 109, 114 (8th Cir. 1981) (en banc)).

Thus, the factors that govern this Court's determination of whether or not to grant Kemin's motion for a preliminary injunction are: (1) reasonable likelihood of success on the merits; (2) irreparable harm; (3) whether the balance of hardships tips in favor of granting a preliminary injunction; and (4) the public interest. Id. "These four factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested." Id. The movant bears the burden of proving that it is entitled to preliminary injunctive relief. Circle R, Inc., 919 F. Supp. at 1287.

"The Federal Circuit Court of Appeals has cautioned that 'a preliminary injunction is a drastic and extraordinary remedy, not to be routinely granted.'" Id. at 1286 (quoting Intel Corp. v. ULSI Sys. Tech. Inc., 995 F.2d 1566, 1568 (Fed. Cir. 1993)). It is purely within the district court's discretion to grant or deny a preliminary injunction in a patent case, and review is made with an eye for abuse of that discretion. PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1560 (Fed. Cir. 1996).

Despite the instruction that no one factor is dispositive, the likelihood of success and irreparable harm factors seem significantly more important. See Reebok Int'l, Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1555-56 (Fed. Cir. 1994) (discussing that while appellate courts prefer the district court to make findings on each of the four preliminary injunction factors "[b]ecause, irrespective of relative or public harms, a movant must establish both a likelihood of success on the merits and irreparable harm . . . , the district court may deny a preliminary injunction based on the movant's failure to establish either of these two crucial factors without making additional findings respecting the other factors."). In fact, in Reebok, the Federal Circuit Court of Appeals explained:

> [w]hile a district court must consider all four factors before granting a preliminary injunction to determine whether the moving party has carried its burden of establishing each of the four, we specifically decline today to require a district court to articulate findings on the third and fourth factors when the court denies a preliminary injunction because a party fails to establish either of the two critical factors.

Id. at 1556 (citing T.J. Smith and Nephew Ltd. v. Consolidated Med. Equip., Inc., 821 F.2d 646 (Fed. Cir. 1987)).

ANALYSIS OF THE PRELIMINARY INJUNCTION FACTORS

A. Likelihood of Success on the Merits.

"In seeking a preliminary injunction pursuant to section 283, a patent holder must establish a likelihood of success on the merits both with respect to validity of its

patent and with respect to infringement of its patent." Hybritech Inc., 849 F.2d at 1451. In this case, PVDC has argued as a defense to the allegation of infringement that the'714 patent is invalid, unenforceable, and, alternatively, not infringed. Thus, with respect to patent '714, the likelihood of success factor is really a two step inquiry: (1) Kemin's likelihood of success over PVDC's assertions of invalidity and unenforceability of the '714 patent; and (2) Kemin's likelihood of success on its claim of infringement by PVDC on the '714 patent.

1. Validity and enforceability of the '714 patent.

A fundamental tenet of the patent law is that once a patent has issued, that patent is presumed valid. 35 U.S.C. § 282. The purpose of this presumption is "to contribute stability to the grant of patent rights." Magnivision, Inc. v. Bonneau Co., 115 F.3d 956, 958 (Fed. Cir. 1997). This presumption applies at every stage of the litigation, including the preliminary injunction stage. Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc., 134 F.3d 1085, 1088 (Fed. Cir. 1998). "The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting it." 35 U.S.C. § 282.

At the preliminary injunction stage, the Federal Circuit Court of Appeals has instructed that the inquiry of the burden placed upon the alleged infringer is "whether the challenger's evidence of invalidity is sufficiently persuasive that it is likely to overcome the presumption of patent validity". PPG Indus., 75 F.3d at 1566 (citing

New England Braiding Co. v. A.W. Chesterton, Co., 970 F.2d 878, 883 (Fed. Cir. 1992). The alleged infringer must provide evidence which creates a "*substantial question*" of invalidity, in support of its invalidity claim, with the court remaining cognizant that this invalidity defense may not be completely developed. New England Braiding, 970 F.2d at 883 (emphasis added).

The presumption of validity arising from section 282 can satisfy the patentee's burden of showing likelihood of success on the merits as to validity where a defendant is unable to create a "substantial question" of invalidity. PPG Indus., 75 F.3d at 1566. Where, as here, the validity of patent '714 has been challenged, "the patentee must show that the alleged infringer's defense lacks substantial merit". New England Braiding, 970 F.2d at 883. The ultimate issue with respect to validity that this Court must decide then, is, in light of the presumption of validity arising from section 282, has PVDC created a "substantial question" of invalidity? PPG Indus., 75 F.3d at 1566. If so, has Kemin met this challenge by showing PVDC's invalidity defense lacks "substantial merit"? New England Braiding, 970 F.2d at 883.

PVDC alleges that patent '714 is invalid for two somewhat interrelated reasons. First, purified lutein crystals protected by the '714 patent were anticipated by prior art, i.e., a 1991 Poultry Science publication (therefore the lutein crystals were not available for patent because they were anticipated by prior art, see 35 U.S.C. § 102, and therefore not novel or new, 35 U.S.C. § 101). The second reason PVDC alleges Kemin's

patent is invalid, or more appropriately, unenforceable, is due to the inequitable conduct Kemin engaged in by not disclosing the 1991 Poultry Science publishing.

a. PVDC's invalidity argument.

Under 35 U.S.C. § 102, a claim is anticipated, and therefore invalid, when a single prior art reference discloses each and every element of the claimed invention. Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715 (Fed. Cir. 1984). However, if the prior art reference fails to suggest even one limitation of the claimed invention, then the claim is not anticipated. Atlas Powder Co. v. E.I. duPont De Nemours & Co., 750 F.2d 1569, 1574 (Fed. Cir. 1984).

PVDC alleges that the Poultry Science article does suggest each and every element of the claimed invention. PVDC points out that the lutein purified in the Research Note is of the same formula as that found in claim 1 of the '714 patent and is derived from a plant extract, marigold petals. PVDC says that because the purity of lutein in the Research Note by High Pressure Liquid Chromatography (HPLC) is 99.2 percent, the product created under the Research Note must essentially be substantially free from other carotenoids. Therefore, all of the limitations of claim 1 of the '714 patent were disclosed by the Research Note, meaning that claim 1 of the '714 patent is invalid.

PVDC also points out that claim 2 of the '714 patent is anticipated by the Poultry Science reference since the lutein is derived from naturally occurring plants

selected from the group consisting of fruits, vegetables, and marigolds. Additionally, PVDC alleges that claim 4 of the '714 patent is anticipated by the Poultry Science reference since the lutein comes from marigold flower extract.

As further evidence that the Poultry Science reference does anticipate claims 1, 2, and 4 of the '714 patent, PVDC points to the European Patent that Kemin obtained in conjunction with the American patent. See PVDC's Exs. K, L, and M. The Court is advised that when this European Patent was granted, the Poultry Science reference (undisclosed by Kemin) was discovered by the European examiner, and the patent that issued did not contain certain claims.[1] Compare PVDC's Ex. K, pp. 4-5 with PVDC's Ex. M, p. 4. Although not entirely clear, PVDC seems to argue that this occurred because the claims not ultimately contained in the European Patent were found to have been anticipated by the Poultry Science reference.

Kemin argues the '714 patent is not anticipated by the Poultry Science article since the article does not disclose each and every element of the claimed invention. Specifically, the Poultry Science article does not disclose purified lutein crystals suitable for human consumption, but rather a process that utilizes an organic solvent to extract purified lutein crystals for use as chicken feed. Kemin points out that one of the basic

[1] At oral argument, the Court inquired regarding the importance of the proceedings on the European patent in reaching conclusions in the present case. PVDC argues that process relates directly and persuasively. Kemin argues different patent office standards and procedures, as well as different questions posed, render the proceedings in Europe of little importance to the present case. The record before this Court is not sufficient to resolve these conflicting arguments.

and novel properties of the ‘714 invention is that the purified lutein crystals are suitable for human consumption, which is not available under the Poultry Science article since organic solvents are used, whose residues apparently remain in the Poultry Science lutein crystals rendering them unfit for human consumption.

Kemin argues the specification of the ‘714 patent supports this position. See Kemin Ex. 1:

> “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.” (Col. 2, ll. 5-10) . . .
>
> “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.” (Col. 3, ll. 17-21) . . .
>
> “. . . [T]he purified lutein is required not to contain even traces of any toxic chemicals . . .” (Col. 4, ll. 16-17).

The specification therefore delineates the importance of the ‘714 lutein crystals being suitable for human consumption. The ‘714 patent uses the transition phrase “consisting essentially of”, which is used to exclude elements that are not specifically listed in the claim which 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, Kemin has specifically excluded anything that would make the resulting purified lutein crystals unsuitable for human consumption, since human

consumption suitability is one of the basic and novel properties of the invention. Therefore, the presence of organic solvents so that the product is unfit for human consumption is excluded, since this would materially alter at least one of the basic and novel properties of the invention. Furthermore, Kemin points out that the Poultry Science reference is directed toward chicken feed and the poultry industry and not the industry creating lutein suitable for human consumption.

Kemin argues that since the Poultry Science article does not disclose the absence of contaminating residual solvents, and thus does not disclose purified lutein suitable for human consumption, the article does fail to suggest limitations of the '714 patent. Therefore, the claims protected by the '714 patent are not anticipated by the Poultry Science article. Atlas Powder Co., 750 F.2d at 1574.

Kemin additionally points out that the Poultry Science reference was not enabling (that is, did not produce what was said would be produced) and therefore cannot be considered legal prior art for anticipation purposes. See In re Borst, 345 F.2d 851, 855 (C.C.P.A. 1965) (discussing that a prior art reference must be sufficient to enable one with ordinary skill in the art to practice the invention in order to be considered legal prior art for anticipation purposes); see also In re Hoeksema, 158 U.S.P.Q. 596, 201 (C.C.P.A. 1968) (indicating that if prior art fails to disclose or render obvious a method of making a claimed compound, it cannot be concluded that the compound itself is within the public's possession). In a sworn affidavit, Chris

Nelson, Kemin Industries Worldwide president, points out that after the Poultry Science reference was published, Kemin set about re-creating the experiment to reproduce the results of the Poultry Science reference. See Kemin Ex. 27. Following the reference precisely, the attempt at reproduction failed, and lutein crystals were never produced using the disclosed method. See id. at ¶ 10.[2]

Lastly, at oral argument, Kemin pointed out significant differences in the claim language used in the American versus European Patent applications as a possible explanation as to why the European patent did not issue with all the claims Kemin originally sought to patent. In the European patent application documents, claims 1, 2, and 4 contain nearly identical language as was used in the American patent application except for a few critical words. Kemin argues this is the reason why the Eurpoean patent that issued did not contain every claim originally pled. Compare PVDC's Ex. K, pp. 4-5 with PVDC's Ex. M, p. 4.

In the American application, claim 1 of the '714 patent reads "[t]he carotenoid composition *consisting essentially of* . . . ." In the European application, claim 1 reads "[a] carontenoid composition *comprising* . . . ." Kemin ultimately argues that the differing language used in the patent applications resulted in the claims being scrutinized differently. See generally PPG Indus., 156 F.3d at 1354 (discussing the differences

[2] Kemin's assertion of no enablement is somewhat undermined by the reality that nearly two years after the issuance of the '714 patent, Kemin did disclose the Poultry Science reference when applying for a patent for the '564 patent. Clearly by this time, Kemin's experiments proved the reference was enabling, or it would not have disclosed the article then either.

between the following three available transition phrases: closed claims, written in "consisting of" terminology; fully open claims, written in "comprising" terminology; and the middle ground between fully open and closed claims, those claims written in "consisting essentially of" terminology, which is generally used to signal a partially open claim).

PVDC responds to Kemin's arguments in the following manner. First, because Kemin argues the Poultry Science reference is not enabling, Kemin cannot really know if the process creates lutein crystals containing harmful organic solvent residue rising to a level that is unsuitable for human consumption. PVDC says it has replicated the Poultry Science reference, and it is suitable for human consumption, despite the presence of organic solvent residue, and thus cannot be avoided by Kemin as prior art.

Responding to Kemin's argument that "suitable for human consumption" is a basic and novel property of patent '714, PVDC says Kemin has violated the general premise of patent law that limitations cannot be read into a claim from the specification. See Toro Co. v. White Consolidated Indus. Inc., 920 F. Supp. 1008, 1015 (D. Minn. 1996) (explaining that while claims are interpreted in light of their specification, statements in the specification should not be read into the claims as limitations). Essentially, PVDC argues that Kemin is pointing to the specification to determine the nature of the limitation (suitable for human consumption) rather than the scope of the limitation.

PVDC then argues that the Poultry Science reference is directed toward purified lutein being used as an analytical standard, which is, according to PVDC, the basic and novel aspect of the '714 patent. PVDC alleges the '714 patent contemplates uses of the lutein which are broader than just being "suitable for human consumption", specifically, use of the compound as an analytical standard.

PVDC points to the specification for the '714 patent (Col. 3, ll. 26-29) which reads that "[l]utein, in pure form may be used as an analytical standard and in cancer prevention trials, and as a safe effective color additive in human food". Thus, PVDC argues the '714 patent cannot be read to strictly limit the claimed composition to that suitable for human consumption.

PVDC argues that the compound disclosed by the Poultry Science article was also intended for use as an analytical standard (rather than for use as chicken feed), as the Poultry Science article specifically indicates that "[t]he poultry industry and its suppliers of carotenoids would like to adopt HPLC analysis for use in the purchase and sale of carotenoids, but the lack of adequate carotenoid standards has discouraged this . . .". See PVDC Ex. H, p. 651. "Lutein and its diesters prepared by the current method have been used successfully as chromatographic markers, as standards in quantitative analysis . . . ." Id. at 653. Since the Poultry Science reference and the '714 patent contemplate use of the compound as an analytical standard, PVDC argues

the Poultry Science reference is anticipating prior art, invalidating at least claims 1, 2, and 4 of the '714 patent.[3]

b. PVDC's unenforceability defense.

In order to best serve the public, "the most effective patent examination occurs when, at the time an application is being examined, the [Patent and Trademark] Office is aware of and evaluates the teachings of all information material to patentability". See 37 C.F.R. § 1.56(a) (2002). Therefore, "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith . . . which includes a duty to disclose to the Office all information known to that individual to be material to patentability . . .". Id. Information is defined as "material" when it is not cumulative to information already of record or being made of record in the application, or if, by itself or in combination with other information, a prima facie case of unpatentability of a claim is demonstrated. See 37 C.F.R. § 1.56(b).

"Inequitable conduct includes affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." Baxter Int'l Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998). Determining whether conduct may be classified as inequitable requires a two-step analysis. Id. First, the court determines if the withheld reference

[3] Somewhat diminishing the effect of this argument by PVDC is that the Poultry Science article specifically discusses that "the ready availability of a single carotenoid, lutein would help greatly because lutein is the major carotenoid in typical poultry diets and tissues", apparently diluting PVDC's claim that this article was intended solely to create an analytical standard. See PVDC Ex. H, p. 651.

meets the initial level of being "material". Id. If the court finds the reference was material, then the court must go on to determine whether the evidence shows a threshold level of intent to mislead the PTO. Id.

"Materiality and intent to deceive must be proven by clear and convincing evidence." Catalina Lighting, Inc. v. Home Depot, USA, Inc., 295 F.3d 1277, 1288 (Fed. Cir. 2002) (quoting Upjohn Co. v. Mova Pharm. Corp., 225 F.3d 1306, 1312 (Fed. Cir. 2000)). Finding that intent to deceive exists "cannot be inferred solely from the fact that the information was not disclosed; there must be a factual basis for a finding of deceptive intent". Upjohn Co., 225 F.3d at 1312 (quoting Hebert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996)).

PVDC points to Paragon Podiatry Lab. v. KLM Lab., Inc., 984 F.2d 1182, 1189 (Fed. Cir. 1993), for the premise that "where the level of materiality is high, intent may be inferred". A district court finding that both materiality and intent to deceive either do or do not exist is reviewed by the Federal Circuit Court of Appeals under the clearly erroneous standard of Federal Rule of Civil Procedure 52(a). Baxter Int'l Inc., 149 F.3d at 1327.

If both materiality and intent are established, then the court is to weigh these two things against one another. Id. "The more material the omission, the less evidence of intent will be required in order to find that inequitable conduct has occurred." Id.

Viewing all the circumstances, a determination must then be made as to whether the conduct is so culpable as to find that the patent should be held unenforceable. Id.

PVDC's argument of materiality, as well as their argument regarding the intent of Kemin in not submitting the Poultry Science reference, presupposes the reference anticipates, claim for claim, claims 1, 2, and 4 of the '714 patent. PVDC has submitted an affidavit of its expert, Ronald Daignault, who claims the reference "clearly" anticipates claims 1, 2, and 4 of patent '714 and that the publication pertained specifically to the purificiation of lutein wherein the end result was near 100 percent by HPLC. See PVDC Ex. J. This ultimately is PVDC's basis for arguing there is a high amount of materiality in the Poultry Science reference.

Kemin argues intent to deceive the PTO is lacking and, additionally, that the Poultry Science reference is not material. Specifically, if a reference is merely cumulative, or is less material than other references already before the examiner, Kemin argues disclosure is not required. Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1582 (Fed. Cir. 1991). Since the background of the invention adequately describes the current state of the art, disclosure of the Poultry Science reference would have been cumulative and, thus, unnecessary. The background of the '714 invention indicates:

> "Marigold flower petals are an excellent source of lutein because they contain high levels of lutein and no significant levels of other carotenoids. Extracts of marigold flowers are commercially available but consist of lutein that is esterfied with fatty acids such as

> lauric, myristic, and palmitic acids. Lutein in its natural form as it exists in marigold flowers does not exist as free lutein. Upon saponification of the marigold extract, the lutein fatty acid esters are converted to lutein. However, the resulting lutein is still contaminated with a number of chemical impurities. To date, no method has been described to isolate and purify the free form of lutein from these chemical impurities."
>
> "The saponified extracts of marigold flower petals are commercially available and currently used in chicken feed to enhance the yellow color of egg yolk and the skin of chickens. However, the extract is not acceptable as a direct color additive for human foods because of the presence of impurities. The availability of substantially pure lutein suitable for human use and the evidence that significant levels of lutein derivatives are normally found in human blood would also make lutein an attractive color additive."

As Kemin indicates in the background of the invention, while lutein had previously been purified, the resulting product was not suitable for human consumption. Therefore, the PTO had been made aware of what the Poultry Science reference provided making that reference cumulative; furthermore, as the reference does not disclose lutein suitable for human consumption, it is not material.

Kemin challenges PVDC's inference of intent with an affidavit from Christopher Nelson, which specifically explains that "the thought never occurred to [Mr. Nelson] to disclose the reference", both because it would be cumulative to the background of the invention, and because the reference was not enabling (did not create what it purported to create). See Kemin Ex. 27, ¶ 11. While there is a strong indication of materiality of the Poultry Science article, PVDC has, so far, utterly failed to provide a basis for concluding any requisite intentional conduct on Kemin's part in not disclosing the

reference. Based on the record before the Court, intentional misconduct on the part of Kemin has not been established.

Therefore, moving on to a comparison of the '714 patent with PVDC's allegedly infringing products, the following observations can be made. When comparing the chemical compound called for in the '714 patent and the chemical compound of PVDC's products, the two appear structurally identical. Compare Kemin Ex. 1 at Col. 9, ll. 1-9 with Kemin Ex. 19, p. 2. Additional similarities exist.

PVDC advertises that its product is "100 percent natural marigold carotenoids". See Kemin Ex. 19. PVDC's products are carotenoid compositions derived from plant extracts as called for in claim 1 of the '714 patent. PVDC marketing indicates its products contain lutein with a purity of 87 percent +/- 2 percent trans-lutein, 10 percent trans-zeaxanthin, and 3 percent other carotenoids. See id. PVDC's expert indicates that PVDC's products contain lutein with a purity of 89 percent +/- 2 percent. See PVDC Ex. J, ¶ 6(f). Kemin performed tests on the PVDC compound with the tests indicating an average lutein purity of 92.63 percent. See Kemin Ex. 24, ¶ 13. The 87 percent +/- 2 percent trans-lutein purity advertised in PVDC's marketing material is a substantially purer form in comparison with lutein found in the matrix of any naturally occurring plant. See Kemin Ex. 24, ¶ 14 (referring to Kemin Ex. 19). PVDC marketing material does not indicate specific percentages of purity of other configurations of lutein, possibly lumping cis-lutein in with the 3 percent other carotenoids – but

which Kemin alleges must be included in calculating the percent total of lutein purity. See id. at ¶ 26. Neither the trans-zeaxathin nor the other carotenoids present materially affect or alter the basic and novel properties of the purified composition for its usefulness as a supplement. See id. at ¶ 26. Therefore, according to Kemin, even using the PVDC marketing material which discloses the least amount of purity of lutein present, the PVDC compound meets each and every limitation of claim 1 of the '714 patent and, literally, infringes claim 1 of the '714 patent.

In light of the obvious chemical similarities between the '714 patent and the chemical formula advertised by PVDC in its marketing material; in light of the similarities in the percentages of "substantially pure" lutein between the products; and in light of the similarities, indeed, identical end uses, of the '714 patent and PVDC products (that is, lutein suitable for human consumption which the consumer takes to avail themselves of the benefits currently associated with lutein), the Court finds Kemin has shown a likelihood of success as to the issue of infringement of the '714 patent by PVDC's products.

Additionally, PVDC has not created a "substantial question" of invalidity of the '714 patent.[4] While a strong indication of materiality of the Poultry Science article exists, PVDC has, so far, failed to provide a basis for concluding any requisite inten-

[4] Ultimately finding that PVDC has not created a "substantial question" of invalidity precludes this Court from deciding whether Kemin has met PVDC's challenge of invalidity by showing PVDC's invalidity defense lacks "substantial merit". See New England Braiding, 970 F.2d at 883.

tional conduct on Kemin's part in not disclosing the reference. Therefore, Kemin has shown a likelihood of success on the issue of enforceability of the '714 patent. As such, Kemin has shown a likelihood of success on the merits with regard to the '714 patent.

2. Kemin's likelihood of success on the merits regarding the '564 patent.

PVDC has alleged that the '564 patent is invalid and, in the alternative, is not infringed by PVDC's process. Therefore, the previously mentioned factors (discussed in the prior '714 likelihood of success factor) apply with equal force here but are not repeated. Analyzing the "likelihood of success" factor as it relates to the '564 patent is less detailed, however, since PVDC has not offered a fully developed argument regarding the invalidity of the '564 patent.

As explained, the '564 patent is a process patent. Therefore, 35 U.S.C. § 295 applies:

> In actions alleging infringement of a process patent based on the importation, sale, offer for sale, or use of a product which is made from a process patented in the United States, if the courts finds –
>
> (1) that a substantial likelihood exists that the product was made by the patented process, and
>
> (2) that the plaintiff has made reasonable efforts to determine the process actually used in the production of the product and was unable to so determine,
>
> the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.

Kemin argues that the purpose of section 295 is clear – the burden-shifting approach recognizes the difficulties U. S. patentees of processes have in enforcing their rights against foreign infringers who use the process to produce products imported into the United States. See generally Pfizer v. F & S Alloys and Minerals Corp., 856 F. Supp. 808, 810 (S.D.N.Y. 1994) (discussing that with section 271(g), Congress amended the patent statutes to prohibit the unauthorized importation, sale, or use of an infringing product manufactured abroad, and that in section 295, Congress set out the burdens of proof for claims brought under section 271(g)). Apparently recognizing that generally these foreign processes will be unavailable to the U. S. patentee, Congress implemented this burden-shifting approach.

Kemin points out that PVDC has been unwilling to disclose its protected trade secret process of creating its purified lutein. While offers have been made between the parties to arrive at a compromise, no agreement has been reached. Kemin asserts that PVDC's position of refusing to allow Kemin's researchers access to PVDC's process is unreasonable considering the following two facts: (1) Kemin's staff must have access to PVDC's process because Kemin's staff will help its attorneys formulate its theory of the case; (2) Kemin's researchers are leaders in the area of human consumable lutein (as evidenced by the '714 and '564 patent) and, thus, perhaps the most knowledgeable and experienced people available to help Kemin's attorneys scrutinize the efficacy of any process disclosed by PVDC. For these reasons, Kemin says it cannot agree with

PVDC's position as recently outlined in PVDC's application for protective order, which would prevent Kemin's attorneys from disclosing PVDC's process to Kemin researchers.

PVDC argues that the process it utilizes to obtain its lutein suitable for human consumption is so elementary that allowing Kemin's researchers access would divulge valuable trade secrets. PVDC therefore has offered a compromise, agreeing to allow Edmund Sease, lead attorney for Kemin, along with one other attorney from Mr. Sease's law firm, and an expert unaffiliated with Kemin, access to PVDC's process. PVDC argues these three people, after even a brief review of PVDC's process, would clearly see PVDC is not infringing on the '564 patent.

So far unable to access PVDC's process, Kemin has tested and analyzed PVDC's lutein to try and discern the PVDC's extraction process. Kemin discovered residual propylene glycol in PVDC's lutein. Kemin alleges the presence of propylene glycol exists because the non-organic solvent is used in the extraction process for lutein. Pointing to the tests conducted, and the purity achieved by PVDC, as well as the telltale signs of propylene glycol present, Kemin argues there is a substantial likelihood that PVDC's process infringes on patent '564.

As an indication of reasonable efforts to determine PVDC's process, Kemin points out it has conducted studies looking for propylene glycol which would not be found but for being used in PVDC"s extraction process. Kemin says this testing is the

only reasonable method available to determine whether PVDC infringes the ‘564 patent, considering PVDC will not disclose its process. Although there is a difference in the amount of propylene glycol found in the Kemin lutein product versus the PVDC lutein product, Kemin reasons this difference does not matter, as evidenced by PVDC selling its product as a substitute for Kemin’s product, and PVDC approaching certain Kemin customers, including H. Reisman Corporation. Thus, Kemin argues, the presumption of infringement arising under section 295 should apply to Kemin’s benefit.

PVDC counters by arguing that Kemin does not know PVDC’s process, and the mere presence of propylene glycol means nothing. PVDC points out that Kemin has no evidence that PVDC uses propylene glycol at the same ratios, for the same purpose, or at the same point as described in the ‘564 process. Furthermore, PVDC points out the concentrations of propylene glycol differ, with Kemin’s having nearly two times as much propylene glycol residue in their process as does PVDC’s. Essentially, PVDC argues that while it uses propylene glycol in its process, Kemin’s own studies show that residue concentrations differ between Kemin and PVDC products. This fact leads to the conclusion that less propylene glycol than is used by Kemin is used by PVDC, and, thus, the ratios of reactants disclosed in claim 1 of the ‘564 patent are not used by PVDC, leading to the inevitable conclusion that PVDC does not infringe.

PVDC also offers expert testimony that PVDC “does not first admix propylene glycol with the oleoresin at a temperature of 50-60 degrees C, and then adding a base

for saponification". This opinion, though, is somewhat questionable, since PVDC readily admits only two people know of PVDC's process and challenges Kemin for making various conclusions of PVDC's process solely by examining the finished product – which is apparently what PVDC's own expert had to work with in arriving at his opinion.

PVDC points out that the patent examiner issued the '564 patent due to Kemin using propylene glycol followed by alkali treatment, and that PVDC does not use propylene glycol followed by alkali treatment. Moreover, because PVDC uses propylene glycol following the saponification prior to dilution with water, a smaller amount of propylene glycol is used than that contained in step (b) of the '564 patent. These differences, including PVDC not following elements contained in step (a) nor the range of propylene glycol provided in step (b) of the '564 patent, PVDC argues, equate to substantial differences and, thus, a process that does not infringe the '564 patent.

As an initial matter, this Court agrees that Congress, when drafting section 295, would have had in mind the difficulties United States patentees of processes have in enforcing their rights against foreign infringers who use the process to produce products imported into the United States. However, the Court finds Kemin has failed to make the necessary showing under 35 U.S.C. § 295 either that a "substantial likelihood exists that the product was made by the patented process" or that Kemin has "made

reasonable efforts to determine the process actually used in the production of the product". See 35 U.S.C. § 295.

Under the circumstances, this Court does not believe an adequate record exists upon which to conclude what the PVDC process is. The fact that PVDC's end product contains propylene glycol is interesting, but it cannot be conclusive without further information regarding why and how the material becomes a component. While an effective argument might ultimately be made that it is necessary for Kemin to obtain access for their in-house scientists to the PVDC process, this discovery dispute impedes the creation of a record to support a finding of substantial likelihood the PVDC process is infringing. The information exchange offered by PVDC may be less than optimum for Kemin's litigation ultimate purposes, but it would logically make a significantly greater contribution to this threshold question. Without taking a step of that sort, the Court must conclude Kemin has not made reasonable efforts to clarify the process actually used by PVDC for purposes of the current motion.

While Kemin, as the patentee, has every right "to urge the court to apply § 295 when circumstances warrant it . . .", "the court has every right to exercise its discretion in determining at what point in the decisional process the statute will be brought into play". See Nutrinova Nutrition Specialties & Food Ingredients GMBH v. Int'l Trade Comm'n, 224 F.3d 1356, 1360 (Fed. Cir. 2000). For these reasons, with respect to the '564 patent, Kemin has failed to prove "that a substantial likelihood exists that"

PVDC's "product was made by the patented process" and that it "has made reasonable efforts to determine the process actually used in the production of the product and was unable to so determine". See 35 U.S.C. § 295. Therefore, the benefit of the burden-shifting approach of section 295 is unavailable to Kemin at this stage. In the absence of that burden shifting and on the current record, the Court cannot find there is likelihood of success on the claim of infringement of the '564 patent.[5]

B. Irreparable Harm.

As Kemin correctly points out, a presumption that irreparable harm will occur arises upon a clear showing of validity and infringement. Smith Int'l v. Hughes Tool Co., 718 F.2d 1573, 1581 (Fed. Cir. 1983). Under the record before the Court, Kemin

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[5] The Court pauses briefly to discuss the doctrine of equivalents. In this case, propylene glycol does exist in the PVDC product, but at different levels than in the Kemin product. Additionally, most of PVDC's defenses to infringement of the '564 patent relate to what it sees as "substantial differences" between the PVDC process and the Kemin process. Due to these "substantial differences" between the processes, PVDC argues, its process does not infringe the '564 patent. This Court makes no determination as to whether Kemin's '564 patent is infringed by PVDC's process via the doctrine of equivalents. While something may not literally infringe a patent, a finding of infringement may still exist via the doctrine of equivalents where unimportant and insubstantial changes or substitutes are used; otherwise, an infringer could avoid infringement by simply making small changes in the act of copying. Festo Corp. v. Shoketzu Kinzoku Kogyo Kabushiki Co., Ltd., 122 S. Ct. 1831, 1837 (May 28, 2002). Therefore, the scope of a patent is not limited to its literal terms, but instead embraces all equivalents to the claims described. See id. (citing Winans v. Denmead, 56 U.S. (15 How.) 330, 347 (1954). Kemin specifically did not waive any argument it has regarding the doctrine of equivalents. See Kemin Memo in Support of Motion for Preliminary Injunction, pp. 12-13 (discussing that "a full range of equivalents is available . . . although Kemin does not believe the doctrine of equivalents is even needed") (citations omitted). However, neither party has created a sufficient record which would allow this Court to make an adequate determination as to whether PVDC's perceived "substantial differences" are so unimportant or insubstantial to warrant a finding that PVDC infringes the '564 patent via the doctrine of equivalents. For this reason, Kemin has also not shown a likelihood of success on the issue of infringement via the doctrine of equivalents.

is entitled to the benefit of this presumption. While no other showing of harm is required, Kemin does point to further indications that irreparable harm will result unless this preliminary injunction is granted.

Kemin emphasizes that it will suffer harm which money damages could never adequately remedy. Kemin acquired the rights to the '714 patent through Kemin Industries, Inc., its affiliate company, and The Catholic University of America. Both Kemin Industries, Inc., and The Catholic University of America receive royalty payments from Kemin for the production of these purified lutein crystals. In addition, purified lutein crystals have now been incorporated into different vitamin supplement formulations, such as Centrum, the leading multi-vitamin in the United States.

Having been incorporated into major vitamin formulations could continue to spawn the acceptance of lutein and the growth of the purified lutein crystal market. The trademark FloraGLO® identifies Kemin's purified lutein crystal product and is the only ingredient logo on Centrum's multi-vitamins. Since incorporating FloraGLO® into Centrum, Kemin has signed "logo agreements" with 79 different companies who will now display the FloraGLO® trademark on the products incorporating Kemin's free-form lutein crystals.

Kemin has heavily invested in research and development costs regarding the lutein protected by patent '714. Since 1995, over $1-million has been expended for internal research and development. Kemin has funded approximately $1-million to

outside organizations such as the Harvard Medical School, Tufts University, Johns Hopkins University School of Medicine, and the Department of Veterans Affairs Medical Center in North Chicago, Illinois, for research related to new processes for making lutein, new uses for lutein, and to determine the health benefits associated with lutein. In the recent past, Kemin's lutein crystals have achieved the Generally Recognized as Safe designation by the FDA, which opens a substantial new market for Kemin's lutein – food and beverage manufacturers (with the lutein being used as a food colorant, for instance). Kemin invested more than $1-million during its process of obtaining the GRAS designation from the FDA.

Kemin has also funded a campaign to increase public awareness of lutein and its benefits. As some indication of its success of increasing the public's awareness, Kemin points to a study from Market Facts in 2001 indicating that 44 percent of Americans were aware that lutein is an anti-oxidant linked to good eye health, compared to only 5 percent of Americans in 1999.

A potential infringer, with no need to recoup any of the foregoing research and development costs, would be in position to undercut Kemin's price for lutein. Potential infringers could enjoy the benefits of the public's awareness of lutein without having expended energy, time, and resources into building this awareness. In light of the recently available market for food and beverage products, potential infringers now have additional incentives to infringe.

PVDC has admitted approaching current customers of Kemin. Should this injunction not issue, and others are encouraged to infringe, Kemin's role in the market-place could suffer tremendously. Such a loss in marketplace position supports a finding of irreparable harm. Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1367-68 (Fed. Cir. 2001).

Finally, PVDC admits to having no substantial assets in the United States. Kemin research has not uncovered any appropriate registration with the Texas Secretary of State for PVDC, despite PVDC marketing literature providing a Texas address for "PVDC USA". The attendant uncertainties associated with Kemin ever collecting money damages from PVDC after trial is a factor tending to show the potential for irreparable harm. Lambton Mfg. Ltd. v. Young, 833 F. Supp. 610, 616-17 (W.D. Ky. 1993) (pointing out that defendant had no substantial assets in the United States to satisfy a money judgment in finding irreparable harm and granting a preliminary injunction).

With respect to patent '714, under the record before this Court, given the Court's findings on validity, enforceability, and infringement, Kemin is entitled to the presumption that irreparable harm will arise. Furthermore, Kemin has produced additional indications that support finding the second preliminary injunction factor is in

Kemin's favor. In considering the '564 patent, based upon the record before the Court, the issue is mooted by Kemin's inability to show likely success on the merits.[6]

C. Balance of Hardships.

Having established the probable validity and infringement of the '714 patent and the potential irreparable harm Kemin will suffer if this injunction does not issue, this Court is afforded considerable discretion in deciding preliminary injunctions. Data-scope Corp. v. Kontran, Inc., 786 F.3d 398 (Fed. Cir. 1986).

PVDC points out that it is a company located in a relatively poor area of Mexico. Though it has built a business around the poultry feed additives market, over the last ten years, PVDC has invested resources and money into producing more highly purified lutein. These investments were made in good faith, and if enjoined from selling purified lutein suitable for human consumption, PVDC will lose these investments and could suffer irreparable financial losses.

If the injunction is denied, Kemin will still be able to collect monetary damages from PVDC should Kemin succeed at trial on the merits. Eliminating PVDC from the human consumable lutein marketplace, by way of injunction, would require PVDC to forfeit all the resources invested up until now and start over. Moreover, due to the

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[6] For this reason, the remaining two preliminary injunction factors are not analyzed with respect to the '564 patent. See Reebok Int'l, Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1556 (Fed. Cir. 1994) (explaining that the Federal Circuit Court of Appeals "specifically decline[d] . . . to require a district court to articulate findings on the third and fourth factors when the court denies a preliminary injunction because a party fails to establish either of the two critical factors" (citing to T.J. Smith and Nephew Ltd. v. Consol. Med. Equip., Inc., 821 F.2d 646 (Fed. Cir. 1987).

very small percentage of the marketshare PVDC has made (less than 2 percent), compared to Kemin's marketplace share, requiring PVDC to forfeit all of its investment in the United States market outweighs any hardship suffered by Kemin.

On the other hand, the sole product Kemin is devoted to is the production of the '714 patented purified lutein crystals, in various forms, through the process protected by the '564 patent. Kemin, in an effort to create the purified lutein market, has greatly invested in research and development, has increased the public's awareness of the benefits of lutein, and has protected these efforts by securing patent rights. Kemin's narrow business focus tips this factor in its favor. Mentor Graphics Corp. v. Quickturn Design Systems, Inc., 999 F. Supp. 1388, 1394 (D. Ore. 1997), *aff'd*, 150 F.3d 1374 (Fed. Cir. 1998) (concluding a company patentee focusing on one product would suffer economic loss and market share loss if the preliminary injunction were not granted). This is especially true where, as here, Kemin does not suggest that the broader historical focus of PVDC's business, creation of pigments for the poultry industry, infringes on either the '564 or the '714 patents. This balance tips to the benefit of Kemin.

D. The Public Interest.

One of the essential properties of protecting intellectual property is to allow inventors to reap the benefits of their labor by preventing others from practicing what they have invented. E.I. duPont de Nemours Co. v. Polaroid Graphics Imaging, Inc.,

706 F. Supp 1135, 1146 (D. Del. 1989). The public's interest always benefits through the encouragement of research and development when presumptively valid patents are enforced. Given the conclusions made as to patent '714, the fourth factor also tips in Kemin's favor.

CONCLUSION

The '714 Patent.

The Court concludes that with respect to the '714 patent, PVDC has not generated a substantial question of invalidity. Although there is a strong indication of materiality of the Poultry Science reference, PVDC has not established a sufficient basis for concluding there was the requisite intentional conduct on behalf of Kemin in not disclosing the article. Thus, Kemin has demonstrated a likelihood of success on the issue of enforceability of the '714 patent. Therefore, the presumption that an issued patent is a valid patent carries the day for Kemin. Additionally, due to the similarities in the chemical structures and purity percentages of the lutein at issue, combined with the end use similarities between the '714 patented product and the PVDC product, Kemin has demonstrated a likelihood of success in its allegations that PVDC infringes upon the '714 patent.

This Court is led then to the presumption that Kemin could potentially suffer irreparable harm based upon Kemin's clear showing of patent validity and infringement. Moreover, lest any doubt exists as to the irreparable harm factor, Kemin has offered

additional indicia of the potential for irreparable harm, buttressing this Court's finding that the irreparable harm preliminary injunction factor is in Kemin's favor.

The third preliminary injunction factor, balance of hardships, tips in Kemin's favor primarily due to the narrow business focus of Kemin, compared with the historically broader business focus of PVDC. Finally, the public interest will be furthered by enforcement of Kemin's intellectual property rights in the '714 patent. Because all four factors in the analysis of whether a preliminary injunction should issue in a patent case weigh in favor of Kemin, its motion for preliminary injunction as in relation to the '714 patent is hereby **granted**.

The '564 Patent.

With respect to the '564 patent, the Court declines to apply the burden shifting provided by 35 U.S.C. § 295, as Kemin has not established a substantial likelihood that PVDC's products were made by the process protected by the '564 patent, or that it has made reasonable efforts to determine the process actually used and was unable to so determine. Therefore, with respect to the '564 patent, Kemin has not demonstrated the likelihood of success factor tips in its favor. For related reasons, Kemin has therefore failed to demonstrate it faces the threat of irreparable harm with respect to the '564 patent. Because the two most important preliminary injunction factors have not been established by Kemin, its motion for preliminary injunction in relation to the '564 patent is hereby **denied**.

Having determined a preliminary injunction should issue with respect to the '714 patent, the Court must address the amount of an appropriate bond. Fed. R. Civ. P. 65(c). The record indicates PVDC had approximately $500,000.00 in relevant sales during 2002, constituting a modest share of the United States market for this material. Projecting the likely duration of this litigation, the Court concludes a bond in the amount of $100,000.00 should adequately protect the Defendant from costs and damages should it later be determined that the restraint was wrongful.

Therefore, the Court hereby **ORDERS** that, pursuant to Fed. R. Civ. P. 65, Defendant PVDC, their officers, agents, servants, employees, and attorneys, and those in active concert or participation with them or Defendants, **ARE HEREBY RESTRAINED AND ENJOINED** from continuing to infringe United States Patent No. 5,382,714, including by making, using, importing, or selling within the United States purified lutein crystals from plant extracts.

The above Preliminary Injunction is effective at 12:01 a.m. (C.S.T.) on January 6, 2003, and upon Kemin Foods filing an undertaking in the sum of $100,000.00, and shall remain in effect during the pendency of this action.

IT IS SO ORDERED.

Dated this 2nd day of January, 2003.