IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

KEMIN FOODS, L.C. and THE CATHOLIC UNIVERSITY OF AMERICA Plaintiffs, v. OMNIACTIVE HEALTH TECHNOLOGIES, INC. and OMNIACTIVE HEALTH TECHNOLOGIES PRIVATE, LTD Defendants	)	Case No. 8:07-cv-1308-T-33TGW **DEMAND FOR JURY TRIAL**

DEFENDANT OMNIACTIVE HEALTH TECHNOLOGIES LIMITED'S ("OMNIACTIVE INDIA") ANSWER AND COUNTERCLAIMS TO PLAINTIFFS' KEMIN'S FIRST AMENDED COMPLAINT

Defendant OmniActive Health Technologies Limited ("OmniActive India") hereby states its Answer and Counterclaims to the First Amended Complaint of Plaintiffs Kemin Foods, L.C. and The Catholic University of America (“Plaintiffs") as follows, wherein each numbered paragraph in the following Answer responds to the identically numbered paragraph of the First Amended Complaint:

ANSWER

JURISDICTION AND VENUE

1. OmniActive India admits the allegations contained in Paragraph 1 of the First Amended Complaint.

2. OmniActive India admits the allegations contained in Paragraph 2 of the First Amended Complaint.

3. OmniActive India denies the allegations contained in Paragraph 3 of the First Amended Complaint.

4. OmniActive India admits that OmniActive USA has made sales to customers in Florida, but denies all other allegations contained in Paragraph 4 of the First Amended Complaint.

THE PARTIES

5. OmniActive India admits the allegations contained in Paragraph 5 of the First Amended Complaint.

6. OmniActive India admits the allegations contained in Paragraph 6 of the First Amended Complaint.

7. OmniActive India admits that OmniActive USA is a corporation duly organized and existing under the laws of the State of Delaware and that its principle place of business is located at 51 JFK Parkway, First Floor West, Short Hills, NJ 07078.

8. OmniActive India states that its proper legal name is OmniActive Health Technologies Ltd but otherwise admits the allegations in Paragraph 8 of the First Amended Complaint.

9. OmniActive India denies the allegations in Paragraph 9 of the First Amended Complaint. Responding to the lettered subparagraphs of Paragraph 9 of the First Amended Complaint, OmniActive India states as follows:

a. OmniActive India admits that OmniActive USA was established when OmniActive India decided to begin selling lutein in the United States and admits that the quoted statement was made in an email from a member of OmniActive India's management team. OmniActive India denies all other allegations of subparagraph 9(a) of the First Amended Complaint.

b. OmniActive India denies the allegations of subparagraph 9(b) of the First Amended Complaint.

c. OmniActive India denies the allegations of subparagraph 9(c) of the First Amended Complaint.

d. OmniActive India denies the allegations of subparagraph 9(d) of the First Amended Compliant.

e. OmniActive India denies the allegations of subparagraph 9(e) of the First Amended Complaint.

f. OmniActive India denies the allegations of subparagraph 9(f) of the First Amended Complaint.

g. OmniActive India admits that its personnel occasionally travel to the United States to assist OmniActive USA relating to lutein products. OmniActive India further admits that Hiren Doshi testified that, in his capacity as president of OmniActive USA, he reports to the management team of OmniActive India, and that he relies on OmniActive India for information about the products he sells. OmniActive India denies all other allegations of subparagraph 9(g) of the First Amended Complaint.

h. OmniActive India admits that Hiren Doshi assists OmniActive India with its business in Europe. OmniActive India denies all other allegations of subparagraph 9(h) of the First Amended Complaint.

i. OmniActive India admits that OmniActive USA has a line of credit, but denies all other allegations of subparagraph 9(i) of the First Amended Complaint.

j. OmniActive India admits the allegations of subparagraph 9(j) of the First Amended Complaint.

k. OmniActive India admits the allegations of subparagraph 9(k) of the First Amended Complaint.

l. OmniActive India denies the allegations of subparagraph 9(l) of the First Amended Complaint.

BACKGROUND

10. OmniActive India admits that Lutein has antioxidant properties and has been found to decrease incidence of macular degeneration. OmniActive India is without knowledge or information sufficient to form a belief as to the truth of the other

allegations contained in Paragraph 10 of the First Amended Complaint and, therefore, denies those allegations.

11. OmniActive India admits that OmniActive USA imports and sells Lutemax® Free Lutein in the United States and that OmniActive USA has made sales to customers in Florida. OmniActive India denies all other allegations contained in Paragraph 11 of the First Amended Complaint.

12. OmniActive India denies the allegations contained in Paragraph 12 of the First Amended Complaint. In response to the lettered subparagraphs of Paragraph 12 of the First Amended Complaint, OmniActive USA states:

a. OmniActive India admits that defendants have stated that the products it sells are "manufactured under a fully controlled value chain" and a "fully integrated supply chain," while "the competition" does not. OmniActive India denies that these statements are false or misleading and further denies all other allegations in subparagraph 12(a) of the First Amended Complaint.

b. OmniActive India admits that defendants have stated that the manufacturer of its products "directly manage[s]" quality unlike Kemin/DSM. OmniActive India denies that these statements are false or misleading and further denies all other allegations in subparagraph 12(b) of the First Amended Complaint.

c. OmniActive India admits that defendants have stated that they use Safflower Oil / Sunflower Oil unlike their competitors. OmniActive

India further admits that it has stated Kemin uses Corn Oil in its free lutein products. OmniActive India denies that these statements are false or misleading and further denies all other allegations in subparagraph 12(c) of the First Amended Complaint.

d. OmniActive India admits that defendants have stated that their lutein and/or their facility for manufacturing lutein are ISO, Kosher, and/or Halal certified. OmniActive India denies that these statements are false or misleading and denies all other allegations in subparagraph 12(d) of the First Amended Complaint.

e. OmniActive India admits that defendants have stated the competition uses gelatin in their beadlets. OmniActive India denies that these statements are false and misleading and denies all other allegations in subparagraph 12(e) of the First Amended Complaint.

f. OmniActive India admits that it has stated that Kemin's free lutein product has "the largest percentage of particles in the 100-200 micron range." OmniActive India denies that these statements are false and misleading and denies all other allegations in subparagraph 12(f) of the First Amended Complaint.

g. OmniActive India denies that the defendants ever made the statement alleged in subparagraph 12(g) of the First Amended Complaint and denies that the OmniActive India ever made this statement in the press release attached to the First Amended Complaint at Tab B.

h. OmniActive India denies the allegations in subparagraph 12(h).

OmniActive USA objects to the incorporation by reference of all of Tab B to the First Amended Complaint due to the lack of specificity and clarity of the allegedly false statements.

COUNT ONE – PATENT INFRINGEMENT

13. OmniActive India realleges and incorporates herein its answers to Paragraphs 1 through 12 of the First Amended Complaint.

14. OmniActive India admits that Tab A includes U.S. Patent No. 5,382,714 ("the '714 patent"), that the '714 patent is entitled "Process for Isolation, Purification and Recrystallization of Lutein from Saponified Marigold Oleoresin and Uses Thereof," and that the inventor listed on the face of the '714 patent is Frederick Khachik. OmniActive India denies all other allegations contained in Paragraph 14 of the First Amended Complaint.

15. OmniActive India admits that the assignee listed on the face of the '714 patent is The Catholic University of America. Otherwise, OmniActive is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 15 of the First Amended Complaint and, therefore, denies those allegations.

16. OmniActive India admits that it is not a licensee of the '714 patent, but denies all other allegations in Paragraph 16 of the First Amended Complaint.

17. OmniActive India denies the allegations contained in Paragraph 17 of the First Amended Complaint.

18. OmniActive India denies the allegations contained in Paragraph 18 of the First Amended Complaint.

19. OmniActive India denies the allegations contained in Paragraph 19 of the First Amended Complaint.

COUNT TWO – FALSE MARKING

20. OmniActive India realleges and incorporates herein its answers to Paragraphs 1 through 19 of the First Amended Complaint

21. OmniActive India admits that the '953 patent was issued to Inventor T.K. Sunil Kumar, assigned to Kancor Flavours & Extracts ("Kancor"), and later assigned by Kancor to OmniActive India. OmniActive India further admits that Kancor is a shareholder in OmniActive India. OmniActive India admits that it has advertised its free lutein products as being covered by the '953 patent and has marked products made by OmniActive India with the '953 patent number. OmniActive India denies all other allegations in Paragraph 21 of the First Amended Complaint.

22. OmniActive India denies the allegations contained in Paragraph 22 of the First Amended Complaint.

COUNT THREE – FALSE ADVERTISING

23. OmniActive India realleges and incorporates herein its answers to Paragraphs 1 through 22 of the First Amended Complaint.

24. OmniActive India denies the allegations contained in Paragraph 24 of the First Amended Complaint.

25. OmniActive India denies the allegations contained in Paragraph 25 of the First Amended Complaint.

COUNT FOUR – VIOLATION OF FLA. STAT. § 817.41

26. OmniActive India realleges and incorporates herein its answers to Paragraphs 1 through 25 of the First Amended Complaint

27. OmniActive India denies the allegations contained in Paragraph 27 of the First Amended Complaint.

28. OmniActive India denies the allegations contained in Paragraph 28 of the First Amended Complaint.

29. OmniActive India denies the allegations contained in Paragraph 29 of the First Amended Complaint.

30. OmniActive India denies the allegations contained in Paragraph 30 of the First Amended Complaint.

31. OmniActive India admits that Kemin is one of its competitors in the market for lutein products. OmniActive India denies all other allegations in Paragraph 31 of the First Amended Complaint.

32. OmniActive India denies the allegations contained in Paragraph 32 of the First Amended Complaint.

COUNT FIVE – VIOLATION OF FLA.STAT. § 501.201, et. seq.

33. OmniActive India realleges and incorporates herein its answers to Paragraphs 1 through 32 of the First Amended Complaint.

34. OmniActive India denies the allegations contained in Paragraph 34 of the First Amended Complaint.

35. OmniActive India admits that it competes with Kemin in the market for lutein products. OmniActive USA denies all other allegations in Paragraph 35 of the First Amended Complaint.

36. OmniActive India denies the allegations contained in Paragraph 36 of the First Amended Complaint.

37. OmniActive India denies the allegations contained in Paragraph 37 of the First Amended Complaint.

38. OmniActive India denies the allegations contained in Paragraph 38 of the First Amended Complaint.

COUNT SIX – VIOLATION OF FLORIDA COMMON LAW OF UNFAIR COMPETITION

39. OmniActive India realleges and incorporates herein its answers to Paragraphs 1 through 38 of the First Amended Complaint

40. OmniActive India denies the allegations contained in Paragraph 40 of the First Amended Complaint.

41. OmniActive India admits that it competes with Kemin in the market for lutein products. OmniActive India denies all other allegations in Paragraph 41 of the First Amended Complaint.

42. OmniActive India denies the allegations contained in Paragraph 42 of the First Amended Complaint.

43. OmniActive India denies the allegations contained in Paragraph 43 of the First Amended Complaint

44. OmniActive India denies the allegations contained in Paragraph 44 of the First Amended Complaint.

COUNT SEVEN – PRODUCT DISPARAGEMENT

45. OmniActive India realleges and incorporates herein its answers to Paragraph 1 through 44 of Plaintiff's First Amended Complaint.

46. OmniActive India denies the allegations contained in Paragraph 46 of the First Amended Complaint.

47. OmniActive India denies the allegations contained in Paragraph 47 of the First Amended Complaint.

48. OmniActive India denies the allegations contained in Paragraph 48 of the First Amended Complaint.

49. OmniActive India asserts that the request for a jury trial in Paragraph 49 of the First Amended Complaint is not a factual allegation to which an answer is required.

AFFIRMATIVE DEFENSES

OmniActive states the following affirmative defenses to the allegations in the First Amended Complaint:

FIRST AFFIRMATIVE DEFENSE

50. Plaintiffs have failed to state a claim upon which relief may be granted

SECOND AFFIRMATIVE DEFENSE

51. This Court lacks personal jurisdiction over OmniActive India.

THIRD AFFIRMATIVE DEFENSE

52. Venue is improper in this Court.

FOURTH AFFIRMATIVE DEFENSE

53. The '714 patent is invalid for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, sections 101, 102, 103, and 112.

FIFTH AFFIRMATIVE DEFENSE

54. OmniActive India has not directly infringed any claim of the '714 patent, either literally or under the doctrine of equivalents.

SIXTH AFFIRMATIVE DEFENSE

55. OmniActive India has not contributorily infringed or induced infringement of any claim of the '714 patent.

SEVENTH AFFIRMATIVE DEFENSE

56. Plaintiffs' infringement claims are barred by the equitable doctrines of laches and/or equitable estoppel.

EIGHTH AFFIRMATIVE DEFENSE

57. Plaintiffs are barred from recovering damages, in whole or in part, by reason of Plaintiffs' failure to comply with the requirements of 35 U.S.C. § 287.

NINTH AFFIRMATIVE DEFENSE

58. The ‘714 patent is unenforceable due to inequitable conduct during prosecution of the '714 patent and during prosecution of the reissue patent applications based on the '714 patent. The inequitable conduct includes numerous breaches of the duty of good faith and candor in 37 C.F.R. § 1.56, with deceptive intent, by the inventor and others associated with the filing and prosecution of the '714 patent and the reissue applications based on the '714 patent. The allegations supporting this affirmative defense are set forth with particularity in paragraphs 17-98 of OmniActive India's Counterclaim II, infra, which are incorporated herein by reference and form the basis of this Affirmative Defense.

DEMAND FOR JURY TRIAL

OmniActive India demands a jury trial on all issues properly triable by jury.

COUNTERCLAIMS

For it its counterclaims against Kemin Foods, L.C. and the Catholic University of America, OmniActive India alleges as follows:

THE PARTIES

1. OmniActive Health Technologies Ltd. ("OmniActive India") is a corporation organized and existing under the laws of India, with its principal place of business at A/131, Road No. 23, Wagle Industrial Estate, Thane, Maharashtra, India.

2. OmniActive Health Technologies, Inc. ("OmniActive USA"), is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 51 JFK Parkway, First Floor West, Short Hills, N.J. 07078.

3. Kemin Foods, L.C. ("Kemin") is an Iowa limited liability company, having its principal place of business at 600 East Court Avenue, Suite A, Des Moines, Iowa 50309.

4. The Catholic University of America ("CUA") is a corporation organized and existing under the laws of the District of Columbia, having its principal place of business at 620 Michigan Avenue, NE, Washington, DC 20064.

JURISDICTION

5. These counterclaims arise under the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202), the Patent Laws of the United States (35 U.S.C. §§ 100 et seq.), the Lanham Act (15 U.S.C. § 1125(a)), Florida Statutes § 501.201 et seq., and Florida common law.

6. Jurisdiction in this Court over these counterclaims is proper pursuant to 28 U.S.C. §§ 1331, 1338, 1367, and 2201.

7. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400, and by reason of Kemin's and CUA's choice of forum.

COUNTERCLAIM I – DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND PATENT INVALIDITY

8. OmniActive India incorporates by reference and realleges each of Paragraphs 1 through 7 of its Counterclaims as though fully set forth herein.

9. This counterclaim arises under the Declaratory Judgment Act and the Patent Laws of the United States, more particularly under Title 28 U.S.C. §§ 2201 and 2202 and Title 35 U.S.C. §§ 100, et seq., respectively. This court has jurisdiction under Title 28 U.S.C. §§ 1338 and 2201.

10. An actual and justiciable controversy exists between OmniActive India and Plaintiffs as to the infringement and validity of U.S. Patent No. 5,382,714 ("the '714 patent"), as evidenced by the Amended Complaint and Answer in this action

11. United States Patent No. 5,382,714 ("the '714 patent"), entitled "Process for Isolation, Purification, and Recrystallization of Lutein from Saponified Marigold Oleoresin and Uses Thereof" and issued Jan. 17, 1995 is invalid for failure to comply with the requirements of Title 35 of the United State Code, including without limitation, Sections 101, 102, 103, and 112..

12. OmniActive India has not directly infringed any claim of the ’714 patent, either literally or under the doctrine of equivalents.

13. OmniActive India has not contributorily infringed or induced infringement of any claim of the ’714 patent.

14. Plaintiffs are barred, in whole or in part, from recovery for the alleged infringement by OmniActive India by reason of Plaintiff's failure to comply with the requirements of 35 U.S.C. § 287.

15. Accordingly, to resolve the infringement and validity controversies, this Court should issue judgment declaring that the ’714 patent is not infringed and is invalid.

16. This is an exceptional case under 35 U.S.C. § 285. Accordingly, this Court should award OmniActive India its costs and reasonable attorneys’ fees.

COUNTERCLAIM II – DECLARATORY JUDGMENT OF PATENT UNENFORCEABILITY

17. OmniActive India incorporates by reference and realleges each of Paragraphs 1 through 16 of its Counterclaims as though fully set forth herein.

18. This counterclaim arises under the Declaratory Judgment Act and the Patent Laws of the United States, more particularly under Title 28 U.S.C. §§ 2201 and 2202 and Title 35 U.S.C. §§ 100, et seq., respectively. This court has jurisdiction under Title 28 U.S.C. §§ 1338 and 2201.

19. An actual and justiciable controversy exists between OmniActive India and plaintiffs regarding the unenforceability of U.S. Patent No. 5,382,714 ("the '714 patent") as evidenced by the Amended Complaint and Answer in this action.

20. OmniActive India seeks a declaratory judgment that U.S. Patent No. 5,382,714 ("the '714 patent") is unenforceable due to inequitable conduct by the inventor and others associated with the prosecution of the '714 patent and the prosecution of the reissue patent applications based on the '714 patent.

21. The '714 patent is unenforceable due to inequitable conduct during prosecution of the '714 patent, and during prosecution of five reissue patent applications based on the '714 patent, by individuals associated with the filing and prosecution of the '714 patent application and the reissue patent applications who breached their duty of candor and good faith, with intent to deceive, by (a) withholding material information including material prior art from the patent office, (b) making material misrepresentations to the patent office, (c) filing false and misleading declaration with the patent office, (d) making false material statements to the patent office regarding the Federal Circuit's claim construction, (e) making misleading statements to the patent office about the European counterpart to the '714 patent, and (f) concealing from the patent office the nature of

OmniActive U.S.'s invalidity and unenforceability defenses and the prior art on which they are based.

22. Dr. Frederick Khachik is the named inventor of the '714 patent and was associated with the filing and prosecution of the '714 patent. Dr. Khachik had a duty of candor and good faith to the patent office under 37 C.F.R. § 1.56, which included a duty to disclose information known to him that was material to the patentability of the '714 patent and the reissue patent applications based on the '714 patent.

23. Dr. Christopher Nelson of Kemin Foods supervised, directed, oversaw, and approved the filing and prosecution of the '714 patent. Dr. Nelson had a duty of candor and good faith to the patent office under 37 C.F.R. § 1.56, which included a duty to disclose information known to him that was material to the patentability of the '714 patent..

24. Mark F. Wachter is the patent attorney who filed and prosecuted the five reissue applications based on the '714 patent. Wachter had a duty of candor and good faith under 37 C.F.R. § 1.56, which included a duty to disclose information known to him that was material to patentability of all patent claims examined by the patent office during reissue prosecution.

(A) Inequitable Conduct – The Poultry Science Article

25. Claim 1-4 of the '714 patent are directed to a carotenoid composition that consists essentially of "substantially pure lutein crystals." In Kemin's previous litigation against PIVEG involving the '714 patent, the Court of Appeals for the Federal Circuit construed "substantially pure" to mean "greater than about 90% pure" lutein. Kemin

Foods, L.C. v. Pigmentos Vegetales del Centro de C.V., 93 Fed. Appx. 225, 232 (Fed. Cir. 2004).

26. During prosecution of the '714 patent, Dr. Nelson was very familiar with work done by Tyczkowski and Hamilton relating to purification of lutein from marigold extract. Dr. Nelson supplied materials to Tyczkowki and Hamilton for use in their lutein purification work, and Hamilton sent Nelson his method for purifying lutein.

27. In 1991, Tyczkowski and Hamilton published the results of their research in an article entitled "Research Note: Preparation of Purified Lutein and its Diesters from Extracts of Marigold (Tagetes, erecta)." Poultry Science 10:651-654 (1991) ("the Poultry Science article"). The Poultry Science article disclosed that Tyczkowski and Hamilton, using marigold extract supplied by Kemin, successfully produced lutein crystals that were 99.2% pure lutein. These crystals were "substantially pure" as defined by the '714 patent.

28. Nelson knew about the research disclosed in the Poultry Science article before its publication and also knew of the article itself. Kemin's researchers were experimenting with the method disclosed in the Poultry Science article for years before the application for the '714 patent was filed.

29. The Poultry Science article was material to the patentability of claims 1-4 of the '714 because the article discloses the crystallization of substantially pure lutein crystals, as recited in the patent claims, which are greater than about 90% pure. The Poultry Science article was not cumulative because no other prior art reference considered by the patent office disclosed the lutein crystals with lutein purity as high as the Poultry Science article.

30. Nelson knew of the materiality of the Poultry Science article and chose not to disclose it to the patent office because of its materiality, with deceptive intent, thereby violating the duty of candor and good faith under 37 C.F.R. § 1.56.

31. Nelson's failure to disclose the Poultry Science article to the patent office constitutes inequitable conduct that renders the '714 patent unenforceable.

(B) Inequitable Conduct – Prior Art Lutein Standards

32. Dr. Nelson also knew about, but did not disclose to the patent office, material information about purified lutein standards that were commonly used and commercially available before the alleged invention of the '714 patent. These prior art lutein standards included purified lutein standards made by Kemin Foods and by Sigma Chemical Company.

33. As early as 1989, Kemin researchers under Nelson's supervision were investigating ways to obtain purified lutein. That year, Kemin manufactured higher purity lutein than was claimed by Khachik in the '714 patent, using a modified version of the method eventually published as the Poultry Science article.

34. In December 1989, Nelson gave samples of Kemin's purified lutein standards to Dr. Pat Hamilton of North Carolina State University, Neal Czack of the National Institute of Technology and Standards, and Dr. Neal Craft of the National Bureau of Standards. Nelson's distribution of the Kemin lutein standards constitutes a prior public use of the patented invention under 35 U.S.C. § 102(b).

35. In 1992, Dr. Craft published the results of research that he had conducted using the Kemin lutein standards in an article entitled, "Relative Solubility, Stability, and

Absorptivity of Lutein and β-Carotene in Organic Solvents," 40 Journal of Agriculture and Food Chemistry, 431, 431 (1992) ("the Craft article"). That article reported that Kemin provided pure lutein standards to the author for use in the published study that were greater than 90% pure trans-lutein. In the article, Craft thanked Nelson by name for "the generous gift of lutein." The lutein standards that Nelson provided to Craft were "substantially pure" lutein as that term is used in claims 1-4 of the '714 patent.

36. During prosecution of the '714 patent, Nelson knew that in 1989 Kemin had manufactured substantially pure lutein standards and distributed them to Hamilton, Czack, and Craft, and he also knew that the Craft article, in 1992, had characterized the purified lutein standards as being greater than 90% pure trans-lutein.

37. Nelson had a duty to disclose Kemin's manufacture of the pure lutein standards, the prior public use of the lutein standards by Craft and others, and the Craft article to the patent office during prosecution of the '714 patent. This information was material to the "substantially pure" limitation of claims 1-4, and was not cumulative, because the Kemin purified lutein standards had a higher lutein purity than any prior art that was disclosed to or considered by the patent examiner during patent prosecution.

38. Nelson breached his duty of candor and good faith and committed inequitable conduct by concealing material information about Kemin's pure lutein standards, the public use of those lutein standards, and the Craft article from the patent office with intent to deceive the patent examiner during prosecution of the '714 patent.

39. The '714 patent is unenforceable as a result of Nelson's inequitable conduct relating to Kemin's pure lutein standards and the Craft article.

40. In the late 1980s, Sigma Chemical Company also sold purified lutein standards that consisted of substantially pure lutein crystals that were more pure than any lutein disclosed to the patent examiner during prosecution of the '714 patent. The Sigma lutein standards were prior art to the '714 patent.

41. Chris Nelson knew about the Sigma purified lutein standards during the 1980s and purchased them on Kemin's behalf to calibrate Kemin's HPLC equipment.

42. The Sigma purified lutein standards were material to claims 1-4 of the -714 patent because they consisted of substantially pure lutein crystals that had lutein purity that was higher than any prior art disclosed to or considered by the patent examiner.

43. Nelson had a duty to disclose the Sigma purified lutein standards and Kemin's use of those standards to the patent office in association with the prosecution of the '714 patent.

44. Nelson concealed material information relating to Sigma's purified lutein standards from the patent office with deceptive intent, and thereby engaged in inequitable conduct.

45. As a result of Nelson's inequitable conduct in relation to Sigma's purified lutein standards, the '714 patent is unenforceable.

46. Also in the late 1980's, Hoffman-LaRoche manufactured and distributed purified lutein standards that contained substantially pure lutein crystals. The inventor of the '714 patent, Frederick Khachik, knew about the Hoffman-LaRoche standards during prosecution of the '714 patent and breached his duty of good faith and candor, by

concealing from the patent office, with deceptive intent, material information about the Hoffman-LaRoche standards.

47. Khachik published two articles in 1988 that identify and describe the Hoffman LaRoche purified lutein standards: 36 J. Agric. Food Chem. 929 (1988) ("the Khachik I article"); and 36 J. Agric. Food. Chem 938 (1988) ("the Khachik II article"). Khachik reported in these articles that the Hoffman LaRoche standards were identified by a registry number and that Khachik confirmed their lutein purity by HPLC.

48. Given Khachik's statements about the purity of the lutein in Hoffman LaRoche standards in the Khachik I and Khachik II article, the Hoffman-LaRoche lutein standards were at least 90% pure. Claims 1-4 of the '714 patent were either anticipated by or would have been obvious in view of the Hoffman-LaRoche pure lutein standards and the Khachik I and Khachik II articles. The Hoffman-LaRoche standards and the Khachik articles were therefore material to patentability of claims 1-4 of the '714 patent.

49. The Hoffman LaRoche standards and the Khachik articles were not cumulative because they disclosed lutein of greater purity than any prior art disclosed to or considered by the patent office during prosecution of the '714 patent.

50. Khachik knew of the materiality of the Hoffman LaRoche lutein standards and of his own published articles and chose not to disclose the information to the patent office because of its materiality, with deceptive intent, thereby violating his duty of candor and good faith under 37 C.F.R. § 1.56.

51. Khachik's failure to disclose the prior art Hoffman LaRoche standards and the Khachik I and II articles to the patent office constitutes inequitable conduct that renders the '714 patent unenforceable.

(C) Inequitable Conduct – PIVEG Claim Construction

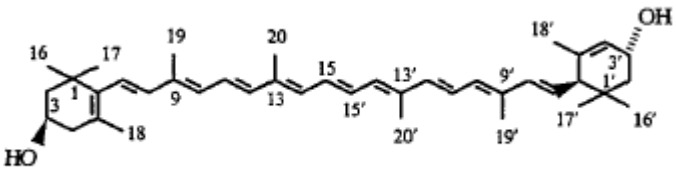
52. The '714 patent is also unenforceable due to inequitable conduct during prosecution of Kemin's five reissue patent application based on the '714 patent. These include reissue applications 11/150,599; 11/702,486; 11/330,423; 11/782,117; and 12/270,303.

53. Under 35 U.S.C. § 251, "[n]o reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent." A reissue claim is broader than the original patent claims if it contains within its scope any conceivable apparatus or process which would not have infringed the original patent. Hockerson-Halberstadt, Inc. v. Converse, Inc., 183 F.3d 1369, 1374 (Fed. Cir. 1999).

54. Although the patent office has not yet granted a reissue patent based on the '714 patent, it has served notices of allowance indicating that the '714 patent will be reissued with most of the original '714 patent claims and new claims 21 and 22 that were filed and prosecuted by Wachter, on Kemin's behalf, during prosecution of the reissue patent applications.

55. During prosecution of the reissue applications, patent attorney Mark Wachter introduced new claim 21, directed to a carotenoid composition, which the Board of Patent Appeals and Interferences (BPAI) indicated should be allowed. The following

table shows claim 1 of the '714 patent side-by-side with reissue claim 21, to facilitate a comparison of the breadth of the claims.

'714 Patent Claim 1	**Reissue Claim 21**
The carotenoid composition **consisting** essentially of	A lutein composition suitable for human consumption which **comprises:**
substantially pure lutein crystals derived from plant extracts that contain lutein, said crystals being of the formula  (3R,3′R,6′R)-β,ε-Carotene-3,3′-diol (Lutein)	at least about 90% lutein having been extracted and purified from plant extracts which contain 10% or less non-lutein carotenoids,
no traces of toxic chemicals* (* term added by Federal Circuit)	no traces of toxic chemicals **that would render the lutein composition unsuitable for human consumption**, and
Wherein the lutein is substantially free from other carotenoids and **chemical impurities found in the natural form of lutein in the plant extract**	significantly less than about 10% of non-lutein carotenoids obtained by purification of said plant extracts.

56. Wachter knew when he filed and prosecuted reissue claim 21 that it was broader than claim 1 of the '714 patent in many ways. First, claim 1 uses the closed transition phrase "consisting essentially of," whereas reissue claim 21 uses the open ended transition "comprises." Second, claim 1 requires substantially pure lutein crystals while reissue claim 21 does not require any crystals but instead, more broadly, would cover a composition that comprises 90% lutein *in any form*, whether or not lutein crystals

are present. Third, claim 1 is limited to the specific trans-lutein molecular structure shown in the claim while reissue claim 21 does not show the lutein structure and implies that coverage may extend to other isomers of lutein beside the trans-lutein specifically claimed in the '714 patent. Fourth, patent claim 1, as construed by the Federal Circuit, excludes even a trace of toxic chemicals while reissue claim 21 qualifies the exclusion to "traces . . . that would render the composition unsuitable for human consumption." Thus, while claim 1 absolutely excludes toxic chemicals, claim 21 would cover compositions that include toxic chemicals in an amount that is not "unsuitable for human consumption." Fifth, while patent claim 1 requires that the crystals be substantially free of non-carotenoid chemical impurities, reissue claim 21 puts no restriction whatsoever on the amount of non-carotenoid impurities, and thus, would cover compositions containing *any amount* of non-carotenoid impurities.

57. During prosecution of the '714 reissue patent applications, Wachter repeatedly made false and misleading statements to the patent office about the scope of the '714 patent, as interpreted by the Federal Circuit, and failed to correct those statements, with deceptive intent, in an effort to persuade the examiner that reissue claim 21 was no broader than claim 21 of the '714 patent.

58. In a preliminary amendment filed in reissue 11/150,599, Wachter stated that new claim 21 was based on the Federal Circuit's PIVEG claim construction of the '714 patent claim 1, stating:

> Claims 21 and 22 are based upon the Federal Circuit's construction of claims 1, 2 and 4 of the '714 patent. In construing said claims to contain "no traces of toxic chemicals" **the Federal Circuit provided *no guidance* as**

> **to what was meant by the term "toxic chemicals".** The '714 patent states at Column 3, lines 17-21 that the purified lutein be "acceptable for human consumption . . . without causing toxic side effects due to residual impurities." Accordingly, Applicant submits that the limitation that the product contain "no traces of toxic chemicals in an amount that would render the lutein product unsuitable for human consumption" is fully supported by the specification and claims of the '714 patent, as construed by the Federal Circuit.

App. No. 11/150,599, Preliminary Amendment, June 10, 2005 (emphasis added). In addition, throughout prosecution of the 11/150,599 application, Wachter argued that "in order to be suitable for human consumption, a composition must inherently meet the standards set by the FDA." App. No. 11/150,599, Amendment, Jan. 11, 2006; Amendment, Nov. 9, 2006 at 18; Khachik Dec., Nov. 4, 2006.

59. When Kemin could not obtain allowance of claim 21, Wachter filed continuation reissue application 11/702,486, on February 5, 2007, repeating and expanding upon its earlier false characterization of the Federal Circuit's decision as one that provided "no guidance" on the "no toxics" limitation, and therefore supported reissue claim 21. This is what Wachter said in the preliminary amendment in the 11/702,486 case:

> In the Litigation, the original claims of the '714 patent have been construed such that ". . .the claimed compositions must contain lutein crystals that are greater than about 90% pure, significantly less than 10% of other carotenoids, and no traces of toxic chemicals." See e.g., Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. DE C.V., 93 Fed. Appx. 225, 232 (Fed. Cir. 2004). Accordingly, claim 21 does not enlarge the scope of the claims of the '714 patent as claim 21 incorporates these limitations from original claim 1 as they have been interpreted and construed by the federal courts.

> Applicant refers to the decision of the Federal Circuit dated March 17, 2004, Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. DE C.V., 93 Fed. Appx. 225, 232 (Fed. Cir. 2004), a copy of which is attached hereto as Appendix III and hereby provided in accordance with 37 C.F.R. § 1.178(b) and 37 C.F.R. § 1.56. In that decision, the Federal Circuit construed claims 1, 2 and 4 of the '714 patent "consistent with the district court's opinion" that the "claimed compositions must contain lutein crystals that are greater than about 90% pure, significantly less than 10% of other carotenoids, and no traces of toxic chemicals." Id. at 232. Applicant also provides the Examiner with a copy of the recent Federal Circuit decision, Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. DE C.V., 464 F.3d 1339 (Fed. Cir. 2006), attached as Appendix IV. In this decision, the Federal Circuit applies the district court's claim construction of claim 1 of the '714 which is based on the Federal Circuit's construction of claims 1, 2 and 4 of the '714 patent. **In construing said claims to contain "no traces of toxic chemicals" the Federal Circuit provided no guidance as to what was meant by "toxic chemicals."** . . . Accordingly, Applicant submits that the limitation that the lutein composition contain "no traces of toxic chemicals that would render the lutein product unsuitable for human consumption" is fully supported by the specification and claims of the '714 patent, as construed by the Federal Circuit.

App. No. 11/702,486, Preliminary Amendment, Feb. 5, 2007 (emphasis added). *See also* App. No. 11/330,423, Preliminary Amendment, Jan. 10, 2006.

60. The patent examiners in reissue application numbers 11/150,599; 11/702,486; and 11/330,423 maintained rejections of the new independent claims, and Kemin filed appeals from the rejections in 11/702,486 and 11/330,423. Kemin fully briefed its arguments and never modified, corrected, or explained to the patent office or that BPAI its earlier false statements about the PIVEG litigation record.

61. After the Federal Circuit issued its PIVEG II decision on September 25, 2006, Wachter had an affirmative duty to disclose to the patent office that the Federal Circuit in PIVEG II expressly rejected the claim construction that Kemin insisted throughout reissue prosecution was supported by the Federal Circuit's construction.

62. Kemin argued in PIVEG II that the "no traces" limitation should be construed to mean no traces in an amount that would be harmful to humans. The Federal Circuit explicitly rejected this proposed construction – now embodied in reissue claim 21 – and narrowly limited the claim to compositions that excluded "any amount" of a toxic chemical. Thus, it was *not* t*rue* that the Federal Circuit provided no guidance as to what was meant by toxic chemicals. In fact, the Federal Circuit considered and rejected precisely the same arguments that Kemin advanced during reissue prosecution. Here is what the PIVEG II court said about Kemin's proposed claim construction:

> In Kemin's view, the phrase "no traces of toxic chemicals" simply requires that the product no contain any chemicals in an amount that would be toxic to a human.
>
> The problem with Kemin's argument is that the '714 patent and our previous construction of claim 1 do not merely exclude toxic amounts of chemicals. **Rather, the patent discusses particular chemicals as 'toxic' and explains that in order to produce lutein for human consumption *one must eliminate any amount* of such chemicals from the lutein product. For example, the patent suggests that methanol and isopropyl alcohol should not be used to produce the patented product because they are toxic. *See '714 patent,* col. 4, ll. 14-19 ("Instead of ethanol, other alcohols such as methanol or isopropyl alcohol may also be employed.** However, since the purified lutein is *required not to contain even traces* of any toxic chemicals, the use of methanol instead of food grade ethanol in this purification process is not normally

> recommended."). We construed claim 1 to require 'no traces' of such chemicals.
>
> **Kemin's argument, both at trial and on appeal, has been that the phrase "no traces of toxic chemicals" should be interpreted as limiting the claim to products in which the levels of all chemicals are below the toxic thresholds set by the Food and Drug Administration**. Neither the patent nor our claim construction, however, makes any reference to toxicity thresholds, whether promulgated by the FDA or otherwise.

PIVEG II, 464 F.3d at 1350 (emphasis added).

63. Wachter does not even hint in the voluminous file histories of Kemin's five reissue applications that the Federal Circuit held that the "no traces" limitation excluded "any amount" of a toxic chemical. Instead Wachter repeatedly reassured the examiner that the Federal Circuit provided "no guidance" on this central question, when in fact the Court rejected the very same interpretation of the no toxic limitation that Wachter wrote into claim 21.

64. The Federal Circuit construed claims 1-4 of the '714 patent to require "no traces of toxic chemicals." Wachter's false statements to the patent office about the Federal Circuit's claim construction in the PIVEG litigation were material to reissue prosecution of claims 1-4 and 21 because they misrepresented the Court's interpretation of "no toxics" in a manner that misled the patent office and resulted in the allowance of reissue claim 21. Claim 21 would not have been allowed if Wachter had told the truth about the Federal Circuit's PIVEG claim construction during prosecution of the reissue applications.

65. Wachter knew that his statements about the Federal Circuit claim construction were false, and chose to make the false statements because of their materiality, with deceptive intent, thereby violating his duty of candor and good faith under 37 C.F.R. § 1.56.

66. Wachter's false statements concerning the Federal Circuit claim construction constitute inequitable conduct that renders unenforceable the '714 patent and any reissue patent based on the '714 patent.

(D) Inequitable Conduct – Breadth of Reissue Claims

67. Wachter falsely stated throughout prosecution of the '714 reissue applications that the reissue claims, including reissue claim 21, were no broader than the claim of the '714 patent. These statements were material to the prosecution of claim 21 because of the rule in 35 U.S.C. § 251 that a claim in a reissue patent cannot be broader than the claims in the original patent if the reissue patent application is filed more than 2 years after the original patent issued.

68. The '714 patent issued on January 17, 1995. The first reissue application based on the '714 patent was not filed until October 2005, more than ten years later.

69. During prosecution of the reissue application 11/150,599, Wachter affirmatively stated in Kemin's Preliminary Amendment that the reissue claims "do not enlarge the scope of the protection of the claims of the '714 patent as the claims have been construed in the [PIVEG] litigation." App. No. 11/150,599, Preliminary Amendment, Oct. 10, 2005. In response to a rejection of claim 21 under 35 U.S.C. § 251, Wachter stated that "claim 21, as amended, is not broader in scope that the original

claims, as they must be interpreted consistent with the construction thereof by the Federal Circuit," even though claim 21 eliminated the requirements that the composition (a) contain lutein crystals and (b) be substantially free of chemical impurities found in the natural form of lutein in the plant extract. App. No. 11/150,599, Amendment, Dec. 1, 2005, at 11; Amendment, Nov. 9, 2006, at 12.

70. Wachter continued prosecution of claim 21 in reissue application number 11/702,486 and said in a preliminary amendment that "claim 21 does not enlarge the scope of the claims of the '714 patent as claim 21 incorporates these limitations from original claim 1 as that they have been interpreted and construed by the federal courts. App. No. 11/702,486, Amendment, Feb. 5, 2007 at 10. This statement by Wachter was false because, with respect to the "no toxics" limitation, Kemin had incorporated in claim 21 the same broadening construction that the Federal Circuit expressly rejected.

71. In response to a rejection of claim 21 under 35 U.S.C. § 251, Wachter again asserted that the claim was no broader than claim 1 of the '714 patent and submitted a misleading declaration from an expert, Kurt Bernhard, which Wachter argued established that claim 21 "clarifies and completes" rather than broadens the original disclosure. App. No. 11/702,486, Amendment, June 26, 2007, at 8; Id. Bernhard Decl.; Id. Amendment, Nov. 5, 2007 at 8 ("this uncontroverted evidence of record mandates a holding that the newly added material in the reissue application specification and claim 21 is not of broader scope than what was originally disclosed in the prior patent and this it is fully supported by the prior patent").

72. On appeal of the rejection of claim 21 to the BPAI, Wachter repeated these same assertions without ever disclosing the clear difference in scope between reissue claim 21 and '714 patent claim 1.

73. Wachter's statements throughout prosecution that claim 21 was not broader than original claim 1 were false because claim 21 was broader than original claim 1, and they were material because claim 21 was not patentable if broader than claim 1. Wachter's filing of the misleading Bernhard declaration was material for the same reason. Wachter knew that the declaration was misleading and material, and that his own statements were false and material, in view of the Federal Circuit's decisions in the PIVEG litigation. Wachter made the statements and filed the declaration with deceptive intent, thereby violating his duty of candor and good faith under 37 C.F.R. § 1.56.

(E) Inequitable Conduct – EP Counterpart to '714 Patent

74. Wachter also committed inequitable conduct by making false, misleading and incomplete statements about the prosecution of EP 067265, the European counterpart to the '714 patent, during prosecution of the reissue applications based on the '714 patent.

75. Wachter mischaracterized the European Patent Office ("EPO") prosecution of EP 067265 during prosecution of reissue 11/702,486, in an effort to persuade the U.S. patent examiner that allowance of claim 21, a composition claim, would be consistent with the actions of the EPO, when exactly the opposite was true.

76. In fact, the EPO rejected all composition claims over the Poultry Science article, and none of those claims was ever allowed. Wachter described the EP prosecution as follows in Kemin's preliminary amendment:

> Applicant desires to make of record related European patent, EP 0672655, which claims priority to the '714 patent and *is* ***consistent with the CAFC*** **[the Federal Circuit]** ***interpretation of the invention*****.**
>
> With respect to the original publication, EP 0672655 A1 (attached as Appendix I), Applicant directs the Examiner to claims 10 and 11, which read as follows:
>
> 10. A carotenoid composition more than 90% of which is lutein and geometric isomers thereof.
>
> 11. A composition of claim 1 or claim 10 more than 97% of which is lutein.

App. No. 11/702,486, Preliminary Amendment, Feb.5, 2007 at 8–9 (emphasis added).

77. Wachter's account of EP 06726 falsely suggests that claims 10 and 11 in the European patent application are somehow part of the allowed EP patent when in fact all of Kemin's composition claims were rejected by the EPO examiner over the prior art and subsequently canceled by Kemin.

78. Wachter knew but did not tell the PTO that (a) claims 10 and 11 of the EP applications were rejected by the patent examiner as unpatentable over the Poultry Science article, File History of EP 067265, Office Action, Nov. 28, 1996; (b) Kemin tried unsuccessfully to overcome the rejection by arguing that the Poultry Science article was inoperable and not enabled, File History of EP 067265, Amendment, Aug. 6, 1997; (c) the EPO examiner refused to withdraw his claim rejections, File History of EP 067265, Office Action, Jan. 13, 1998; and (d), consequently, Kemin withdrew all composition claims from its EP application and none were allowed, File History of EP 067265, Amendment, July 22, 1998..

79. Wachter's statement that the EP patent is "consistent with the CAFC interpretation of the invention" coupled with a recitation without explanation of the canceled composition claims, was false and misleading. The statement was material to the patentability of claims 1-4 and 21 in the reissue patent application because the true facts relating to the prosecution of the EP application are inconsistent with a position that Kemin took in arguing for the f patentability of the reissue claims. 37 C.F.R. § 1.56(b).

80. Wachter knew his statement about the EP application was false and material and chose to make the statement, with deceptive intent, because of its materiality, thereby violating his duty of candor and good faith under 37 C.F.R. § 1.56. Wachter's false and misleading statements about the EP application constitute inequitable conduct that renders the '714 patent unenforceable.

(F) Inequitable Conduct -- The Khachik Declaration

81. Frederick Khachik breached his duty of candor and good faith by filing a misleading declaration during reissue prosecution in order to overcome a prior art rejection.

82. During prosecution of reissue 11/150,599, the PTO examiner rejected claim 21 as anticipated by the Kuzmicky article. App. No. 11/150,599, Office Actions Nov. 3, 2005; May 15, 2006; Oct. 11, 2006; March 27, 2007; and May 24, 2007.

83. In an effort to overcome the Kuzmicky rejection, Wachter filed an amendment based on a declaration from Frederick Khachik asserting that Khachik had attempted to duplicate the work reported in Kuzmicky and "performed an HPLC analysis of the resulting 20 mg xanthophyll fraction and determined that it contained 87% lutein."

App. No. 11/150,599, Amendment, Nov. 9, 2006, at 6 (citing Khachik Dec., Nov. 4, 2006, at ¶ 9). Thus, according to Wachter, Kuzmicky did not anticipate because of its lutein product "not being at least 90% pure." App. No. 11/150,599, Amendment, Nov. 9, 2006, at 22.

84. Wachter's argument and Khachik's declaration were misleading because neither of them disclosed to the patent office that Khachik had calculated the lutein purity of Kuzmicky against the total crystal content, even though Kemin has consistently argued in this case and throughout the PIVEG litigation that lutein purity should be measured only against the carotenoids in the crystal, as opposed to the total crystal.

85. The Khachik declaration reports Dr. Khachik's analysis of a composition that he prepared according to the teachings of the Kuzmicky article. File History of App. No. 11/150,599, Khachik Decl., Nov. 4, 2006. Khachik concluded in his declaration that "the resulting 20 mg xanthophyll fraction ('the Kuzmicky product') was found to be 87% lutein relative to the *other measured compounds* (primarily carotenoids), as determined by high performance liquid chromatography. Id. at ¶ 9 (emphasis added). Exhibit A to Khachik's declaration includes the HPLC results on which Dr. Khachik relies, which show that the only carotenoids identified are lutein and zeaxanthin. Id. at Ex. A p.4. If Khachik had calculated lutein purity according to the claim construction that Kemin argues should apply to this litigation, the lutein purity of the Kuzmicky product would have been 92%, and therefore would have anticipated the claims, rather than 87%.

86. In contrast to Wachter and Khachik's claim construction arguments during reissue prosecution, Kemin has argued in this litigation and in the PIVEG case that lutein

purity is based only on the percentage of lutein compared to the total carotenoid composition, and that it is not measured against non-carotenoid impurities. In its opening claim construction brief in this case, Kemin argues that the claim construction that Dr. Khachik employed in his reissue declaration "could amount to a get out of jail free card for the infringer." (Docket No. 161 at 11-12).

87. Wachter and Khachik knew that Kemin's claim construction in litigation of "substantially pure" was different than the one Khachik employed in distinguishing the Kuzmicky article in his declaration. Kemin's litigation construction was material to reissue prosecution of claims 1-4 and 21 because it refutes and is inconsistent with the position that Wachter and Khachik took in opposing an argument of unpatentability relied on by the patent office.

88. Wachter and Khachik concealed Kemin's litigation claim construction, with deceptive intent, thereby violating their duty of candor and good faith under 37 C.F.R. § 1.56. Their reliance on the misleading declaration and failure to disclose Kemin's litigation claim construction constitutes inequitable conduct that renders the '714 patent unenforceable.

(G) Inequitable Conduct – Concealing Litigation Facts

89. Wachter also breached his duty of good faith and candor by failing to disclose to the patent office during prosecution of the '714 reissue applications that, in this litigation, OmniActive has asserted that the '714 patent is invalid and unenforceable.

90. A person associated with prosecution of a reissue patent application has an affirmative duty to bring to the patent office's attention any litigation involving the

original patent and to describe the nature and basis of any claims of patent invalidity or unenforceability. "As a minimum, the application should call the attention of the Office to the litigation, the existence and the nature of any allegations relating to validity and/or 'fraud', or 'inequitable conduct' relating to the original patent, and the nature of the litigation materials relating to these issues." Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1259 (Fed. Cir. 1997)

91. On August 27, 2007, OmniActive U.S. filed its answer in this litigation asserting invalidity and unenforceability as an affirmative defense and asserting a counterclaim seeking a declaratory judgment of invalidity. (ECF 17).

92. On Oct. 30, 2007, OmniActive U.S. filed answers to the Court's standard interrogatories in this case, asserting in response to interrogatory 3 that the '714 patent was invalid as anticipated or obvious in view of twelve identified prior art references.

93. On July 21, 2008, OmniActive U.S. filed its answer to Kemin's first amended complaint, and asserted a new counterclaim seeking a declaratory judgment that the '714 patent was unenforceable due to inequitable conduct.

94. Although Wachter knew or should have known about the invalidity and unenforceability defenses asserted by OmniActive U.S., he did not disclose the existence of the defenses or their known basis to the patent office during prosecution of the '714 reissue patent applications. Wachter's knowledge of the facts of the case is established by his repeated reference to the litigation during prosecution, which was incomplete and silent as to the invalidity and unenforceability claims.

95. During prosecution of reissue application 11/702,486, Wachter filed an Amendment that said that "another lawsuit involving the '714 patent was filed in the case," but did not disclose OmniActive's invalidity or unenforceability defenses or the prior art and facts upon which those claims were based. Reissue File History 11/702,486, Amendment B at 4-5, Nov. 15, 2007.

96. Likewise, during prosecution of reissue application 12/270,303, Wachter identified this litigation and stated "a motion for summary judgment is pending," but did not say that OmniActive had filed the motion, nor did it identify the invalidity and inequitable conduct defenses asserted by OmniActive or the prior art and facts upon which those defenses were based. Reissue File History 12/270,303, Preliminary Amendment at 9, Nov. 13, 2008.

97. The facts relating to Kemin's litigation with OmniActive were material to the patentability of original claims 1-20 of the '714 patent and reissue claims 21 and 22. Wachter concealed these material facts from the patent office, with deceptive intent, in violation of his duty of good faith and candor under 37 C.F.R. § 1.56. Wachter's failure to disclose this information constitutes inequitable conduct and renders unenforceable the '714 patent and any reissue applications that may be granted based on the '714 patent.

98. This inequitable conduct is an independent reason why this is an exceptional case under 35 U.S.C. § 285 and supports an award to OmniActive India of its costs and reasonable attorneys' fees.

COUNTERCLAIM III: UNFAIR COMPETITION (LANHAM ACT)

99. OmniActive India incorporates by reference and realleges each of Paragraphs 1 through 98 of its Counterclaims as though fully set forth herein.

100. This is a counterclaim for unfair competition arising under the Lanham Act, 15 U.S.C. § 1125(a). Kemin has engaged in unfair competition in violation of 15 U.S.C. § 1125(a).

101. Kemin has made false statements to purchasers and potential purchasers of OmniActive India's lutein products that have actually deceived them, and deterred and intimidated them from purchasing OmniActive India's lutein products or from doing business with OmniActive India's subsidiary OmniActive U.S.A.

102. Kemin's false statements were material in that they are likely to influence purchasing decisions, and Kemin caused these false statements to enter interstate commerce.

103. Kemin's false statements have resulted in actual and probable injury to OmniActive India.

104. Kemin has also brought a meritless and objectively baseless patent infringement lawsuit against OmniActive India and its subsidiary, OmniActive USA, for the sole purpose of injuring OmniActive India and OmniActive USA in competition and deterring customers and potential customers from doing business with them.

105. Kemin's meritless patent suit has resulted in actual and probable injury to OmniActive India in the form of lost sales and profits and attorney fees and costs associated with the defense of the patent suit.

106. Plaintiffs' previously sued Pigmentos Vegetales del Centro S.A. ("PIVEG") in the United States District Court for the Southern District of Iowa for alleged infringement of the '714 patent.

107. On March 17, 2004, the claims of the '714 patent were preliminarily construed by the Federal Circuit to require, among other limitations, that there be "no traces of toxic chemicals." Kemin Foods L.C. et al. v. PIVEG, 93 Fed. Appx. 225, 232 (Fed. Cir. 2004).

108. The Southern District of Iowa adopted the Federal Circuit's construction as its own claim construction. Kemin Foods L.C. et al. v. PIVEG, 319 F. Supp. 2d 939, 943 (S.D. Iowa 2004).

109. Hexane is a toxic chemical. In affirming the jury verdict that PIVEG did not infringe the '714 patent, the Federal Circuit stated: "It is undisputed that PIVEG's products contain some hexane, at levels as high as 23 parts per million. It also appears undisputed that hexane may be considered toxic even in very low concentrations." Kemin Foods L.C.. v. PIVEG, 464 F.3d 1339, 1350 (Fed. Cir. 2006)

110. Kemin argued on appeal "that the phrase 'no traces of toxic chemicals' should be interpreted as limiting the claims to products in which the levels of all chemicals are below the toxic thresholds set by the Food and Drug Administration." Id. at 1350.

111. The Federal Circuit rejected this argument, stating: "The problem with Kemin's argument is that the '714 patent and our previous construction of claim 1 do not merely exclude toxic amounts of chemical. Rather, the patent discusses particular

chemicals as 'toxic' and explains that in order to produce lutein for human consumption one must eliminate any amount of such chemicals from the lutein product. … We construed claim 1 to require 'no traces' of such chemicals." Id. at 1350. The Federal Circuit further stated: "Neither the patent nor our claim construction, however, makes any reference to toxicity thresholds, whether promulgated by the FDA or otherwise." Id.

112. The claims of the '714 patent as properly construed require that there be no detectable level of toxic chemicals present in the claimed lutein composition or the composition resulting from the claimed method.

113. OmniActive India's free lutein products contain safe, but detectable, levels of hexane.

114. Upon information and belief, Kemin had actual knowledge that OmniActive India's free lutein products contained detectable levels of hexane before filing its original complaint in July 2007.

115. Upon information and belief, Kemin had actual knowledge that OmniActive India's free lutein products did not infringe the '714 patent before filing its original complaint in July 2007.

116. Kemin either knew, or should have known, that no OmniActive India free lutein product infringes any claim of the '714 patent before filing its original complaint in July 2007.

117. Despite having actual or constructive knowledge that OmniActive India's free lutein products did not infringe any claims of the '714 patent, Kemin nonetheless filed this patent infringement suit.

118. Before filing this lawsuit, Kemin did not conduct good-faith testing to establish the presence or absence of hexane or other toxic chemicals, despite knowing that any detectable level of toxic chemicals would mean OmniActive India's free lutein product could not infringe the claims of the '714 patent.

119. Instead, Kemin asked an outside firm, Covance Laboratories, to test the OmniActive India sample and to arbitrarily decrease the sensitivity of the test to 10 parts per million ("ppm") even though the test method used by Covance—Headspace GCMS—was capable of detecting hexane at concentrations in the low parts per billion.

120. Kemin rigged the Covance tests to avoid detection of trace concentrations of hexane. Upon information and belief, Kemin knew hexane was present in OmniActive India's free lutein products.

121. Kemin could not have reasonably relied upon these rigged tests from Covance to establish a required claim element: that OmniActive India's free lutein contained "no traces" of hexane.

122. There is nothing in the specification of the '714 patent or the file history that would lead a reasonable person to conclude in good faith that less than 10 ppm of hexane constitutes "no trace" or "not even a trace" of hexane.

123. There is nothing in the Federal Circuit's or the District Court for the Southern District of Iowa's claim construction that would lead a reasonable person to conclude in good faith that less than 10 ppm of hexane constitutes "no trace" or "not even a trace" of hexane.

124. Kemin's claims of infringement of the '714 patent based on the Covance testing were made in bad faith and were objectively baseless given Kemin's manipulation of the levels of detection in the sole testing used to support its claims.

125. Upon information and belief, Kemin has told OmniActive India's free lutein customers and potential customers that the '714 patent gives Kemin alone the right to sell free lutein products in the United States. This statement was false, was known by Kemin to be false, was intended to harm OmniActive India, and place purchasers and prospective purchasers of OmniActive India's free lutein in fear of being sued if they began or continued to purchase OmniActive India's free lutein products. Kemin made this statement for the anticompetitive purpose of intimidating purchasers and potential purchasers from buying lutein products made by OmniActive India or doing business with OmniActive India's subsidiary OmniActive USA

126. Upon information and belief, Kemin has told purchasers and prospective purchasers of OmniActive India's free lutein products that OmniActive India is infringing the '714 patent. This statement was false, was known by Kemin to be false, was intended to harm OmniActive India, and place purchasers and prospective purchasers of OmniActive India's free lutein in fear of being sued if they began or continued to purchase lutein products made my OmniActive India. Kemin made this statement for the anticompetitive purpose of intimidating purchasers and potential customers from doing business with OmniActive USA and purchasing products made by OmniActive India.

127. Kemin has told purchasers and prospective purchasers of OmniActive India's free lutein products that, notwithstanding the limited scope of the '714 patent,

Kemin has obtained allowance of reissue claims that are broader than the patent claims of the '714 patent, and that "significantly strengthens [Kemin's] intellectually property and will help further to protect the FloraGLO market . . ." These statements were false, were known by Kemin to be false, and were intended to harm OmniActive India, and place purchasers and prospective purchasers of OmniActive India's free lutein in fear of being sued if they began or continued to purchase lutein products made by OmniActive India. Kemin made these statements for the anticompetitive purpose of intimidating purchasers and potential purchasers from doing business with OmniActive USA and purchasing lutein products made by OmniActive India.

128. As a result of Kemin's unfair competition in bringing an objectively baseless and meritless patent infringement lawsuit against OmniActive India and its subsidiary OmniActive USA, OmniActive India has been damaged by being forced to incur substantial legal fees and costs associated with the defense of Kemin's frivolous infringement claim, and has also suffered damage in its business in the form of lost sales, lost profits, lost customers, and lost business opportunities.

129. As a result of Kemin's unfair competition in making false and misleading statements to purchasers and potential purchasers of OmniActive India's customers, intimidating those customers from doing business with OmniActive India, OmniActive India has suffered damages in the form of lost sales, lost profits, lost customers, and lost business opportunities.

COUNTERCLAIM IV: UNFAIR COMPETITION (FLA. COMMON LAW)

130. OmniActive India incorporates by reference each of Paragraphs 1 through 129 of its Counterclaims as though fully set forth herein.

131. In violation of Florida common law concerning unfair competition, Kemin made false, objectively baseless statements in bad faith concerning the scope of its patent rights and assertions that OmniActive India infringes the '714 patent, and filed an objectively baseless patent infringement lawsuit against OmniActive India, as referenced in Counterclaim III.

132. Kemin made these statements to deceive customers and injure OmniActive India.

133. Purchasers and potential purchasers of OmniActive India's purified lutein have been misled and deceived by Kemin's false statements.

134. OmniActive India has suffered damages due to Kemin's deceptive and fraudulent conduct including lost sales, lost profits, lost customers, lost business opportunities, and substantial attorney fees and costs associated with the defense of Kemin's frivolous patent infringement suit.

135. Kemin's conduct constitutes unfair competition in violation of Florida common law.

COUNTERCLAIM V – VIOLATION OF FLA. STAT. § 501.201

136. OmniActive India incorporates by reference and realleges each of Paragraphs 1 through 135 of its Counterclaims as though fully set forth herein.

137. In violation of Fla. Stat. § 501.201, et. seq., Kemin has engaged in deceptive and/or fraudulent conduct that has created actual or likely consumer confusion.

138. Kemin's false, objectively baseless, and bad faith assertions to purchasers and potential purchasers of OmniActive India's purified lutein products, referenced in Counterclaim III, have resulted in actual or likely customer confusion, and intimidated and discouraged customers from purchasing purified lutein made by OmniActive India..

139. Upon information and belief, Kemin's violations of this statue were willful, malicious, and made in bad faith for the purpose of harming OmniActive India and hindering competition in the free lutein market.

140. Kemin's violations of this statute have resulted in lost sales and lost potential sales for OmniActive India's free lutein products.

COUNTERCLAIM VI – FALSE PATENT MARKING

141. OmniActive India incorporates by reference and realleges each of Paragraphs 1 through 140 of its Counterclaims as though fully set forth herein.

142. On Jan. 17, 1995, U.S. Patent No. 5,382,714 ("the '714 patent") was issued naming Frederick Khachik as inventor and assigned to The Catholic University of America. Plaintiff Kemin is a licensee of the '714 patent.

143. Although Kemin knows it does not practice the '714 patent, it nevertheless, for the purpose of deceiving the public, has advertised and (upon information and belief) marked and affixed on its lutein products false notice that the products are covered by the '714 patent.

144. Pursuant to 35 U.S.C. § 292(b), OmniActive India is authorized to sue for and hereby sues for the statutory penalty for false marking.

WHEREFORE, OmniActive India prays for judgment against CUA and Kemin as follows:

A. That CUA and Kemin's First Amended Complaint be dismissed with prejudice;

B. That judgment be entered denying CUA and Kemin all relief sought in their First Amended Complaint;

C. That judgment be entered declaring that the '714 patent is invalid, unenforceable, and not infringed by OmniActive India;

D. That judgment be entered declaring this case exceptional under 35 U.S.C. § 285, and awarding OmniActive India its reasonable attorney fees and expenses of litigation against CUA and Kemin;

E. That OmniActive India be awarded all available damages on its Counterclaim for Unfair Competition in Violation of the Lanham Act, including all remedies authorized by 15 U.S.C. § 1117.

F. That OmniActive India be awarded all available damages on its Counterclaim for Unfair Competition under Florida common law, including all remedies authorized by Florida law.

G. That OmniActive India be awarded damages on its Counterclaim for Deceptive and Unfair Trade Practices under Florida Statutes 501.201 et. seq., including punitive damages, attorneys fees, costs, and all other remedies authorized by Florida law.

H. That Kemin be permanently enjoined from making false and deceptive claims about its rights under the ‘714 patent and OmniActive India’s products to OmniActive India’s customers and potential customers.

I. That OmniActive India be awarded its attorneys fees and costs to the extent available under Florida and Federal law;

J. That OmniActive India be awarded statutory damages on its Counterclaim for False Patent Marking under 35 U.S.C. § 292; and

J. That OmniActive India be awarded such other and further relief as this Court shall deem just and proper.

Dated: Aug. 13, 2009

OMNIACTIVE HEALTH TECHNOLOGIES LTD.

Respectfully submitted,

s/ Matthew Goggin
Matthew Goggin (pro hac vice) (MN # 210,705)
Russell J. Rigby (pro hac vice) (MN # 323,652)
CARLSON CASPERS VANDENBURGH & LINDQUIST, P.A.
225 South Sixth Street, Suite 3200
Minneapolis, MN 55402
Phone: (612) 436-9600
Fax: (612) 436-9605
mgoggin@ccvl.com
rrigby@ccvl.com

Nancy J. Faggianelli
Ty Giltinan
CARLTON FIELDS
Corporate Center Three
4221 West Boy Scout Boulevard, Suite 1000
Tampa, Florida 33607
Phone: (813) 223-7000
Fax: (813) 229-4133
nfaggianelli@carltonfields.com
tgiltinan@carltonfields.com

Attorneys for Defendant/Counter-Plaintiff,
OmniActive Health Technologies Ltd.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

KEMIN FOODS, L.C. and THE CATHOLIC UNIVERSITY OF AMERICA, Plaintiffs, v. OMNIACTIVE HEALTH TECHNOLOGIES, INC. and OMNIACTIVE HEALTH TECHNOLOGIES PRIVATE, LTD., Defendants.	)	Case No. 8:07-cv-1308-T-33TGW

CERTIFICATE OF SERVICE

I hereby certify that on August 13, 2009, I caused the following documents:

1. Defendant Omniactive Health Technologies Limited's ("Omniactive India") Answer and Counterclaims to Plaintiffs' Kemin's First Amended Complaint; and
2. Certificate of Service

to be filed electronically with Clerk of Court through ECF, and that ECF will send an e-notice of the electronic filing to the following:

David W. Nelmark
Belin Lamson McCormick Zumbach Flynn
666 Walnut Street, Suite 2000
Des Moines, IA 50309-3989
dwnelmark@belinlaw.com

Robert Ernest Johnson
Gray Robinson, PA
201 N. Franklin St., Ste. 2200
P.O. Box 3324
Tampa, FL 33601
rjohnson@gray-robinson.com

Dated: August 13, 2009

s/Matthew J. Goggin
Matthew J. Goggin