

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

In the Matter of

CERTAIN FOOD SUPPLEMENTS AND
VITAMINS, INCLUDING OCULAR
ANTIOXIDANTS AND COMPONENTS
THEREOF AND PRODUCTS CONTAINING
THE SAME

Inv. No. 337-TA-____

**COMPLAINT OF KEMIN INDUSTRIES, INC. AND KEMIN FOODS, L.C.,
UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED**

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DOCUMENT EXHIBIT LIST

Exhibit No.	Description	Designation
1	Certified copy of United States Patent No. 8,815,955	Public
2	Certified copy of United States Patent No. 9,226,940	Public
3	Certified copy of the Assignment for United States Patent No. 8,815,955	Public
3aC	Copy of recorded Security Agreement for United States Patent No. 8,815,955	Confidential
4	Certified copy of the Assignment for United States Patent No. 9,226,940	Public
4aC	Copy of recorded Security Agreement for United States Patent No. 9,226,940	Confidential
5	Kemin Annual Report	Public
6	http://omniactives.com/operations	Public
7C	Declaration of Rich Heil	Confidential
7aC	Asset Spreadsheet	Confidential
7bC	Process Improvement Spreadsheet	Confidential
7cC	Profit and Loss Statement (2013-2016)	Confidential
7dC	Salary and Personnel Summary (2013-2016)	Confidential
8	OmniActive Press Release at http://omniactives.com/press-releases/omniactive-showcases-lutemax-and-capsimax-ranges-of-products-at-biotaiwan-2015	Public

Exhibit No.	Description	Designation
9	7/18/16 Press Release, “OmniActive Introduces What’s Your B.L.U.E.? To Natural Products Industry Members at ENGREGA 2016”	Public
10	Excerpt from OmniActive marketing campaign entitled “Lutein for Every Age,” at www.luteinforeveryage.com	Public
11	GNC Preventative Nutrition “Eye Health Formula” with 20mg Lutemax 2020 Lutein (including receipt)	Public
12	Doctor’s Best “Best Lutein Dietary Supplement” with Lutemax 2020 Lutein and Zeaxanthin (including receipt)	Public
13	Claim Chart Comparing Independent Claim 1 of US Patent No. 8,815,955 to Exemplary Accused Product of Proposed Respondent (Lutemax® 2020)	Public
13a	OmniActive White Paper: Lutein for Every Age	Public
13b	OmniActive blog “Are you doing everything you can for your eyes”	Public
13c	Nutrition Express Lutein Order listing lutein and zeaxanthin from Lutemax® 2020 as ingredients	Public
13d	Omni’s Lutein for Every Age marketing campaign – pregnancy through infancy	Public
13e	Omni’s Lutein for Every Age marketing campaign – aging	Public
13f	OmniActive White Paper: Protecting from Blue Light with Lutein and Zeaxanthin	Public
13g	Special Edition: OmniActive Insights Newsletter; The Molecular Carotenoids: An Overview	Public
14	Claim Chart Comparing Independent Claim 1 of US Patent No. 9,226,940 to Exemplary Accused Product of Proposed Respondent (Lutemax® 2020)	Public

Exhibit No.	Description	Designation
14a	OmniActive “What’s Your B.L.U.E.” marketing brochure	Public
14b	Nutrition Express Lutein Order listing lutein and zeaxanthin from Lutemax® 2020 as ingredients	Public
14c	Omni’s Lutein for Every Age marketing campaign – pregnancy through infancy	Public
14d	Omni’s Lutein for Every Age marketing campaign – aging	Public
14e	OmniActive White Paper: Protecting from Blue Light with Lutein and Zeaxanthin	Public
14f	Special Edition: OmniActive Insights Newsletter; The Molecular Carotenoids: An Overview	Public
15	Claim Chart Comparing Independent Claim 1 of US Patent No. 8,815,955 to Kemin Foods’ Domestic Industry Product, FloraGLO® Lutein	Public
15a	Age-Related Eye Disease Study 2 Summary	Public
15b	Kemin “Don’t Lose SIGHT of Eye Protection” brochure	Public
15c	Kemin “Beat the Blue” marketing brochure	Public
15d	Kemin’s website	Public

Exhibit No.	Description	Designation
16	Claim Chart Comparing Independent Claim 1 of US Patent No. 9,226,940 to Kemin Foods' Domestic Industry Product, FloraGLO® Lutein	Public
16a	Kemin's website	Public
16b	Kemin "Beat the Blue" marketing brochure	Public
16c	Kemin technical literature: The Role of Lutein in Pregnancy and Infant Care	Public
17C	Declaration of Elizabeth Nelson	Confidential
18C	Letter from John Kolleng	Confidential
19C	Amended and Restated Security Agreement	Confidential

PHYSICAL EXHIBIT LIST

Exhibit No.	Description	Designation
PX-1	GNC Preventative Nutrition Eye Health Formula, together with the receipt of purchase	Public
PX-2	Doctor's Best "Lutein with Lutemax 2020," together with the receipt of purchase	Public

APPENDICES

Appendix No.	Description	Designation
A	Prosecution History for U.S. Pat. No. 8,815,955	Public
B	Cited References for U.S. Pat. No. 8,815,955	Public
C	Prosecution History for U.S. Pat. No. 9,226,940	Public
D	Cited References for U.S. Pat. No. 9,226,940	Public

I. INTRODUCTION

1. Kemin Industries, Inc. (“Kemin Industries”) and Kemin Foods, L.C. (“Kemin Foods”) (collectively, “Kemin” or “Complainants”)¹ respectfully file this Complaint pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based upon the unlawful and unauthorized importation into the United States, the sale for importation, or the sale within the United States after importation, of certain supplements and vitamins, including ocular antioxidants, such as certain lutein and zeaxanthin-based supplements, and components thereof and products containing the same, the use of which infringe at least one claim of each of U.S. Patent Nos. 8,815,955 (“the ’955 patent”) and 9,226,940 (“the ’940 patent”) (collectively “the Asserted Patents”), which are valid and enforceable United States patents. Certified copies of the ’955 patent and the ’940 patent accompany this Complaint as Exhibits 1 and 2, respectively. Certified copies of the assignments of the Asserted Patents, demonstrating that Kemin Industries is the owner of the Asserted Patents by assignment, are attached as Exhibits 3 and 4, respectively.

2. Kemin Industries is a family-owned, Iowa-based innovator in the health and nutrition industry, committed to researching, developing, and manufacturing high-quality supplements and food ingredients. Kemin Industries is also a member of a group of companies that includes Kemin Foods, which acts as the manufacturing, marketing, and selling company responsible for the sale of dietary supplements on a global basis. Kemin Industries and Kemin Foods are sister companies wholly owned by Kemin Worldwide Holdings, Inc., a South Dakota corporation. Through their innovative and

¹ Exhibit 17C [Declaration of Elizabeth Nelson].

diverse product portfolio that includes health-related products, Complainants touch and improve the lives of nearly 2.5 billion people worldwide each year. Complainants' innovative work has resulted in roughly 64 patents in the United States, and 193 patents throughout the rest of the world.

3. The Asserted Patents involve technology in the field of ocular health. Specifically, the Asserted Patents relate generally to the protection of the retina from damage due to harmful blue light and ultraviolet light by the use of ocular antioxidants, such as lutein and zeaxanthin.

4. Complainants have invested significant resources into the development of a domestic industry in articles that are protected by the Asserted Patents. This domestic industry includes food supplements and vitamins including ocular antioxidants that practice at least one claim of each of the Asserted Patents.

5. Proposed Respondents are OmniActive Health Technologies ("OmniActive India") and OmniActive Health Technologies, Inc. ("OmniActive USA") (collectively "OmniActive" or "Proposed Respondents").

6. Proposed Respondents directly and/or indirectly infringe at least one claim of each of the Asserted Patents identified below and as further detailed in ¶¶ 37, 41-42, 44-45. The asserted claims are:

U.S. Patent No.	Asserted Claims
8,815,955	1-13
9,226,940	1-13

7. Proposed Respondents' activities with respect to the importation into the United States, the sale for importation into the United States, and/or the sale within the United States after importation of the Accused Products, as defined in paragraph 1 above and as described more fully in Section V below, are unlawful under 19 U.S.C.

§ 1337(a)(1)(B)(i), in that they constitute the infringement of one or more valid and enforceable claims of the Asserted Patents, and that a domestic industry as required by U.S.C. §§ 1337(a)(2) and (3) exists in the United States relating to the technology protected by the Asserted Patents.

8. Complainants seek relief from the Commission in the form of a limited exclusion order excluding food supplements and vitamins including ocular antioxidants the use of which infringe at least one claim of each of the Asserted Patents and which are manufactured by or on behalf of, imported by or on behalf of, sold by importation by or on behalf of, or sold after importation by or on behalf of any Proposed Respondents, or any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns, from entry for consumption into the United States, entry for consumption from a foreign trade-zone, or withdrawal from a warehouse for consumption, for the remaining terms of the Asserted Patents, except under license of Complainant or as provided by law.

9. Complainants further seek as relief cease and desist orders that prohibit Proposed Respondents and any of their principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) or majority-owned business entities, successors, and assigns, from either directly engaging in or for, with, or otherwise on behalf of Proposed Respondents, (A)

importing or selling for importation into the United States food supplements and vitamins including ocular antioxidants, the use of which infringe at least one claim of each of the Asserted Patents; (B) marketing, distributing, offering for sale, selling, or otherwise transferring, in the United States imported food supplements and vitamins including ocular antioxidants, the use of which infringe at least one claim of each of the Asserted Patents; (C) advertising imported food supplements and vitamins including ocular antioxidants and methods for reducing retinal damage with the same, the use of which infringe at least one claim of each of the Asserted Patents in the United States; (D) soliciting U.S. agents or distributors for imported food supplements and vitamins including ocular antioxidants, the use of which infringe at least one claim of each of the Asserted Patents; or (E) aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer, or distribution of food supplements and vitamins including ocular antioxidants, the use of which infringe at least one claim of each of the Asserted Patents.

10. Complainants seek a bond imposed upon importation of infringing food supplements and vitamins including ocular antioxidants and components thereof and products containing the same, during the 60-day Presidential review period pursuant to 19 U.S.C. § 1337(e), (f), and (j).

11. Complainants further seek any other relief the Commission is authorized to grant and deems appropriate.

II. THE PARTIES

A. Complainants

12. Kemin Industries is an Iowa corporation having its principal place of business at 2100 Maury Street, Des Moines, Iowa 50317. It was incorporated in Iowa on March 11, 1963. Kemin Foods, doing business as Kemin Health, is also an Iowa limited liability company with its principal place of business at 2100 Maury Street, Des Moines, Iowa 50317. It is the manufacturing, marketing and selling arm for Kemin Industries' ocular antioxidants. Kemin Industries and Kemin Foods are sister companies wholly owned by Kemin Holdings, a South Dakota corporation.

13. Kemin is a pioneer in the research and development of high-quality supplements and food ingredients to promote consumer health, the subject matter of the asserted '955 and '940 patents. In 1961, R.W. Nelson and Mary Nelson founded Kemin as a family business in their Iowa home with a manufacturing plant in an old wool barn. From its humble beginnings through today, Kemin has remained committed to the manufacture and research and development of innovative agricultural and health-related products to aid the food, health, nutrition and personal care markets. Over fifty years later, Kemin remains a family-owned, Iowa-based business, but has grown into a worldwide market leader, with seven divisions, including human nutrition and health, agricultural ingredients for feed and biosecurity, pet foods, food products, and personal care.

14. Kemin has a long and storied history of innovation. Since the 1960s, Kemin has conducted research to develop innovative agricultural products, beginning with mold inhibitors and flavors, quickly growing to encompass a full line of ingredients

for animal feed throughout the United States. Kemin expanded its business in the late 1990s to include dietary supplements based on marigold flowers grown for Kemin in India. In 2008, Kemin assembled a specialty crop group to develop highly valued specialty crops, focused on selecting and developing proprietary plant breeds with sustainable sources of novel, highly efficacious molecules that have strong antioxidant and antimicrobial activities. In addition, Kemin continues to innovate in the areas of ingredients for pet food, human food, animal feed, personal care and a line of products supporting horticultural applications, sharing similar molecular platforms and technologies.

15. In the 1980s Kemin shifted its research and development focus to expand beyond the animal feed industry into the human food industry, working to inhibit mold and bacteria in human food and to develop antioxidants. Kemin built a new innovation center in 1983 in Des Moines to continue to study molecules and understand how they worked inside living organisms. By 1992 Kemin had expanded to sell antioxidants in the pet food industry. In addition, Kemin has developed new food technologies to keep edibles fresher and more flavorful, as well as pharmaceutical dyes with colorants that are naturally derived and nutraceuticals that maintain wellness, improve eye and cognitive health, aid weight loss, and enhance athletic power.

16. For more than five decades, Kemin has been dedicated to using plant science to create specialty ingredients, including those that enhance nutrition and health for humans and animals. Kemin has developed proprietary technology to gently retrieve ingredients from their source plants for greater retention of their effective properties,

employing various extraction methods, including a process that uses only purified water, centrifugation and driers.

17. With the advances disclosed in the '955 and '940 patents, Complainants have discovered the importance of protecting the human eye from damage due to the ever-increasing abundance of blue and ultraviolet light produced by televisions, computer monitors, and mobile devices. This technology has now formed an integral part of Complainants' business platform. A copy of Kemin's Annual Report accompanies this Complaint as Exhibit 5. Further information regarding Complainants' products and services can be found at Complainants' website www.kemin.com.

18. Complainants operate principally within the United States, with their facilities located in Des Moines, Iowa devoted to research, development, manufacturing, packaging and distribution of lutein and zeaxanthin products, including FloraGLO®. Complainants devote significant resources to continued innovation within the United States and derive significant revenue from their activities in North America (primarily the United States). For further details relating to such facilities and activities, See Ex. 7C [Confidential Declaration of Rich Heil].

B. Proposed Respondents

19. On information and belief, OmniActive India is a corporation organized under the laws of India with its principal place of business at Phoenix House, T-8, A Wing, 462 Senapati Bapat Marg, Lower Parel, Mumbai – 400 013, India.

20. On Information and belief, OmniActive India is the parent company of OmniActive USA and other OmniActive entities.

21. On information and belief, OmniActive USA is a corporation organized under the laws of Delaware with its principal place of business at 67 East Park Place, Suite 500, Morristown, NJ 07960. On information and belief, OmniActive USA is a wholly owned sales subsidiary of OmniActive India, and is an importer and/or distributor of the Accused Products that are sold under brand names such as Lutemax[®] 2020. See, e.g., Ex. 6 [<http://omniactives.com/operations>] and Ex. 8 [<http://omniactives.com/press-releases/omniactive-showcases-lutemax-and-capsimax-ranges-of-products-at-biotaiwan-2015>] (“The company’s manufacturing operations are located at multiple sites in India and are cGMP and HACCP system compliant.”).

22. On information and belief, OmniActive India has imported the Accused Products and is responsible, directly or indirectly, for at least OmniActive USA’s infringing activities. OmniActive India owns and/or controls manufacturing and sales subsidiaries that manufacture, import, and/or distribute the Accused Products sold under brand names that OmniActive USA owns or licenses. See, e.g., Exs. 8 and 9. OmniActive India also owns and/or controls manufacturing facilities at which the Accused Products may be made under contract. See *id.*

III. THE PRODUCTS AT ISSUE

A. The Technology

23. In general, the lens of the human eye focuses light like a magnifying glass onto the macula (the pigmented area near the center of the retina), and acts as a prism to separate the wavelengths of visible light into blue light, green light, and red light. Blue light, which has the highest wavelength and energy level, is focused on the front of the macula. When this high energy light contacts the sensitive tissue of the retina, it results

in the generation of harmful free-radicals and reactive oxygen species. These free-radicals and reactive oxygen species can cause considerable damage to the photoreceptors in the retina, and result in vision loss. This potential for damage has become an even greater concern, given the increasing abundance of blue and ultraviolet light, which is emitted by computer screens, mobile devices, and LED lightbulbs. Moreover, the blue and ultraviolet light can be particularly problematic when a subject exhibits certain ocular conditions such as astigmatism, hyperopia (farsightedness), or presbyopia (age-related farsightedness). In such subjects, the light is not properly focused onto the retina and high-energy blue light improperly becomes focused directly on the sensitive tissue of the retina.

24. The Asserted Patents generally relate to methods of using ocular antioxidants (including, but not limited to, lutein and zeaxanthin) to prevent and treat damage to the eye due to light. Specifically, the Asserted Patents claim methods of treating or reducing the potential for such damage due to blue light through the use of ocular antioxidants, including macular carotenoids such as lutein, zeaxanthin, and zeaxanthin isomers.

B. The Accused Products

25. The Accused Products are generally supplements and food ingredients that include macular carotenoids (such as lutein, zeaxanthin, and zeaxanthin isomers) that have been sold for importation, imported, and/or sold after importation by Proposed Respondents in the United States for use to support eye health specifically by acting as powerful antioxidants and filtering high-energy blue light. Ex. 9 [7/18/16 Press Release, “OmniActive Introduces What’s Your B.L.U.E.? To Natural Products Industry Members

at ENGREDA 2016”] and Ex. 10 [Excerpt from OmniActive marketing campaign entitled “Lutein for Every Age,” at www.luteinforeveryage.com]. Pursuant to 19 C.F.R. § 210.12(a)(12), specific non-limiting examples of the Accused Products include an OmniActive product sold under the trade name Lutemax[®] 2020, components thereof, and products containing the same. See Exs. 11 and 12 [labels of products containing Lutemax 2020, including GNC Preventative Nutrition “Eye Health Formula” and Doctor’s Best “Best Lutein Dietary Supplement”].

IV. THE PATENTS AT ISSUE

A. The ’955 Patent (U.S. Patent No. 8,815,955)

1. Identification of the Patent and Ownership by Kemin Industries

26. Kemin Industries owns by valid assignment the entire right, title, and interest in the ’955 patent entitled, “Method of Treating Ocular Disorders,” which issued on August 26, 2014.² See Ex. 1. The ’955 patent issued to inventor Richard Roberts from United States Patent Application No. 13/238, 939, filed on September 21, 2011. It expires on April 15, 2032.

27. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the ’955 patent is attached as Exhibit 1. Pursuant to Commission Rule 210.12(a)(9)(ii), a certified copy of the recorded assignments of the ’955 patent is attached as Exhibit 3.

28. Pursuant to Commission Rule 210.12(c), four copies of the prosecution history of the ’955 patent, as well as four copies of each patent and applicable pages of each technical reference mentioned in the prosecution history, are attached as Appendices

² Kemin Industries owns all right, title, and interest in the asserted patents. See Exs. 3, 3aC, 4, 4aC, 18C, and 19C.

A and B, respectively. A certified copy of the prosecution history has been requested from the U.S. Patent and Trademark Office and will be provided to the Commission upon receipt.

2. Non-Technical Description of the '955 Patent

29. The '955 patent has thirteen claims: one independent claim and twelve dependent claims.

30. The '955 patent generally relates to methods of treating ocular disorders with ocular antioxidants, and more particularly to treating increased age-related macular degeneration ("AMD") in subjects, including subjects with hyperopia or astigmatism, with ocular antioxidants.³ AMD is a disease associated with aging that gradually destroys the central region of the retina (the macula), and results in the loss of sharp, central vision, and even blindness. It has been discovered that blue light (such as the light from LED light bulbs, computer screens, and mobile device screens) contributes to the destruction of the macula. The invention claimed in the '955 patent consists of a new and important method of preventing such damage (and associated vision loss) by the administration of ocular antioxidants (such as lutein, zeaxanthin, and zeaxanthin isomers). These ocular antioxidants help form a protective coating over the retina to prevent penetration and damage by harmful blue light.

B. The '940 Patent (U.S. Patent No. 9,226,940)

1. Identification of the Patent and Ownership by Complainant

31. Kemin Industries owns by valid assignment the entire right, title, and interest in the '940 patent entitled, "Method of Treating Ocular Disorders," which issued

³ The text of this Complaint is not intended to interpret the meaning or limit the scope of the claims of the Asserted Patents.

on January 5, 2016.⁴ The '940 patent issued to inventor Richard Roberts from United States Patent Application No. 14/307,684, filed on June 18, 2014. The '940 patent is a divisional of United States Patent Application No. 13/238,939, filed on September 21, 2011, which claims priority to United States Provisional Application No. 61/384,958, filed on September 21, 2010. The '940 patent expires on September 21, 2031.

32. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '940 patent is attached as Exhibit 2. Pursuant to Commission Rule 210.12(a)(9)(ii), a certified copy of the recorded assignment of the '940 patent is attached as Exhibit 4.

33. Pursuant to Commission Rule 210.12(c), four copies of the prosecution history of the '940 patent, as well as four copies of each patent and applicable pages of each technical reference mentioned in the prosecution history, are attached as Appendices C and D, respectively. A certified copy of the prosecution history has been requested from the U.S. Patent and Trademark Office and will be provided to the Commission upon receipt.

2. Non-Technical Description of the '940 Patent

34. The '940 patent has thirteen claims: one independent claim and twelve dependent claims.

35. The '940 patent generally relates to methods of reducing blue and ultraviolet light damage to the eye of subjects, including in subjects with certain eye conditions (namely, presbyopia, hyperopia, or astigmatism), by administering ocular antioxidants. Blue and ultraviolet light is emitted by LED light bulbs, computer screens,

⁴ Kemin Industries owns all right, title, and interest in the asserted patents. See Exs. 3, 3aC, 4, 4aC, 18C, and 19C.

and mobile devices, which have become increasingly ubiquitous. The blue and ultraviolet lights, however, have the shortest wavelengths, and as a result, exhibit the highest energy and greatest potential to induce damage to the eye by absorption of photosensitizers and/or induction of free radicals. It has been discovered that blue light contributes most significantly to the destruction of the macula in subjects with conditions such as astigmatism, hyperopia, or presbyopia. The invention claimed in the '940 patent consists of a new and important method of preventing such damage (and associated vision loss) by the administration of ocular antioxidants (such as lutein and zeaxanthin). These ocular antioxidants help form a protective coating over the retina to prevent penetration and damage by harmful light.

V. SPECIFIC INSTANCES OF IMPORTATION AND SALE

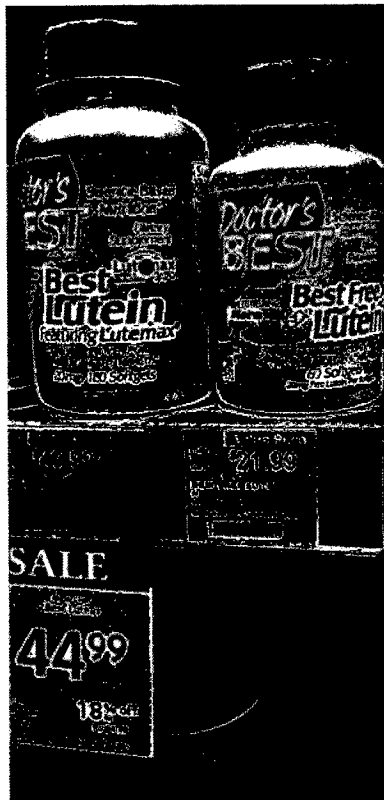
36. On information and belief, one or more of Proposed Respondents manufacture the Accused Products and pertinent components thereof in India. See, e.g., Ex. 6 [<http://omniactives.com/operations>] and Ex. 9 [<http://omniactives.com/press-releases/omniactive-showcases-lutemax-and-capsimax-ranges-of-products-at-biotaiwan-2015>] (“The company’s manufacturing operations are located at multiple sites in India and are cGMP and HACCP system compliant.”).

37. On information and belief, one or more of Proposed Respondents, directly or through agents acting on behalf of Proposed Respondents or their customers, directly or indirectly infringe the Asserted Patents by manufacturing, importing into the United States, selling or offering for sale for importation into the United States, and/or selling within the United States after importation the Accused Products, containing lutein and zeaxanthin supplements, including Lutemax 2020[®]. These Accused Products are

available throughout the United States at major mass retailers, including General Nutrition Centers (“GNC”) and the Vitamin Shoppe. See, e.g., Exs. 11 and 12. The specific instances of importation of the Accused Products set forth below are examples of the unlawful importation and/or sale after importation of infringing articles.

38. As a first example, Complainants obtained from a General Nutrition Center store in Des Moines, Iowa, a sample of GNC Preventative Nutrition Eye Health Formula (model number 00722112), which explicitly states that it contains the Accused Products, 20 mg OmniActive brand lutein supplements (Lutemax[®] 2020 Lutein). Ex. 11. A physical example of the GNC Preventative Nutrition Eye Health Formula, together with the receipt of purchase within the United States, is submitted as Physical Exhibit PX-1.

39. As a second example, Complainants obtained from a Vitamin Shoppe in Des Moines, Iowa, a sample of Doctor’s Best “Lutein with Lutemax 2020” (model number 753950003705), which explicitly states that it contains the Accused Products, 20 mg OmniActive brand lutein supplements and 4 mg zeaxanthin (Lutemax[®] 2020 Lutein). Ex. 12 (see excerpt below, a lutein supplement containing Lutemax[®] 2020, sold next to a lutein supplement containing FloraGLO[®]).



40. A physical example of the Doctor's Best "Lutein with Lutemax 2020," together with the receipt of purchase within the United States, is submitted as Physical Exhibit PX-2.

41. In addition, Proposed Respondents engage in a specific marketing campaign intending to promote and direct the use of lutein and zeaxanthin products to protect and treat the eye using the Accused Products. For example, in a campaign entitled "What's Your B.L.U.E.?", Proposed Respondents explain that blue light "bombards our eyes daily," and can reach "deep into the eye and can harm the macula." See Ex. 9. Proposed Respondents continue that "Lutein and zeaxanthin isomers are known as the 'macular carotenoids' and support eye health by acting as powerful antioxidants and filtering high-energy blue light." *Id.* Proposed Respondents instruct that "Lutemax 2020 is lutein with enhanced levels of zeaxanthin isomers ... to help

protect the eyes against harmful high-energy blue light.” Id. On information and belief, Proposed Respondents have actively engaged and encouraged existing and potential customers to promote and direct the use of lutein and zeaxanthin products to protect and treat the eye using the Accused Products. On information and belief, Proposed Respondents have provided existing customers with marketing materials, including the “What’s Your B.L.U.E.?” marketing campaign materials. Further, Proposed Respondents’ existing customers have used these materials to promote and direct the use of lutein and zeaxanthin products to protect and treat the eye using the Accused Products. On information and belief, Proposed Respondents’ existing customers actively promote and direct the use of lutein and zeaxanthin products to protect and treat the eye using the Accused Products, including publishing marketing materials prepared by Proposed Respondents.

42. The Accused Products are sold for importation, imported into the United States, or sold after importation into the United States.

43. Discovery is expected to reveal additional specific acts of Proposed Respondents’ importation, sale for importation, or sale after importation of the Accused Products.

VI. UNLAWFUL AND UNFAIR ACTS COMMITTED BY PROPOSED RESPONDENTS—PATENT INFRINGEMENT

44. On information and belief, OmniActive India manufactures abroad, sells for importation into the United States, and/or imports into the United States, and OmniActive USA sells within the United States after importation, Accused Products that infringe at least one claim of each of the Asserted Patents.

45. In addition, OmniActive is aware of the Asserted Patents because these patents were specifically identified in a July 20, 2016 correspondence from Complainants to them that preceded the filing of this Complaint, and because OmniActive filed a Complaint for declaratory judgment in the United States District Court for the District of New Jersey based on the Asserted Patents on August 15, 2016. OmniActive directly or indirectly infringes the Asserted Patents by making, using, selling, offering for sale, and importing articles covered by claims of the Asserted Patents. Moreover, OmniActive is aware of the Asserted Patents, at least because it was provided with a copy of this Complaint via registered mail as of the date of its filing.

A. The '955 Patent

46. On information and belief, the Accused Products infringe 1-13 of the '955 patent.

47. Further, on information and belief, OmniActive induces other users of the Accused Products to infringe claims 1-13 of the '955 patent with the specific intent to encourage their infringement by, *inter alia*, marketing the Accused Products, and by creating and/or distributing supplements, food ingredients, and/or similar materials (including carotenoids such as lutein and zeaxanthin) with instructions on using the Accused Products.

48. Further, on information and belief, OmniActive contributes to the infringement of claims 1-13 of the '955 patent because, *inter alia*, OmniActive knows that the Accused Products embody a material part of the claimed inventions of the '955 patent, that they are specially made or specially adapted for use in an infringement of these claims, and that they are not staple articles of commerce suitable for substantial

non-infringing use. For example, on information and belief, the Accused Products use lutein and zeaxanthin, among others.

49. Further, on information and belief, at least some users of the Accused Products use the Accused Products in a manner that directly infringes at least one claim of each of the Asserted Patents.

50. A sample claim chart comparing the asserted independent claim 1 of the '955 patent to the Accused Products is attached as Exhibit 13.

B. The '940 Patent

51. On information and belief, the Accused Products infringe claims 1-13 of the '940 patent.

52. Further, on information and belief, OmniActive induces other users of the Accused Products to infringe claims 1-13 of the '940 patent with the specific intent to encourage their infringement by, *inter alia*, marketing the Accused Products, and by creating and/or distributing supplements, food ingredients, and/or similar materials (including carotenoids such as lutein and zeaxanthin) with instructions on using the Accused Products.

53. Further, on information and belief, OmniActive contributes to the infringement of claims 1-13 of the '940 patent because, *inter alia*, OmniActive knows that the Accused Products embody a material part of the claimed inventions of the '940 patent, that they are specially made or specially adapted for use in an infringement of these claims, and that they are not staple articles of commerce suitable for substantial non-infringing use. For example, on information and belief, the Accused Products use lutein and zeaxanthin, among others.

54. Further, on information and belief, at least some users of the Accused Products use the Accused Products in a manner that directly infringes at least one claim of each of the Asserted Patents.

55. A sample claim chart comparing each asserted independent claim of the '940 patent to the Accused Products is attached as Exhibit 14.

56. In summary, Proposed Respondents unlawfully sell for importation, import, and/or sell after importation into the United States Accused Products, and products containing the same, that directly or indirectly infringe at least the patent claims listed below:

U.S. Patent No./ Accused Products	Asserted Claims	Independent Claims	Accused Parties	Infringement Type
8,815,955 (Roberts) Accused Ocular Antioxidant Products	1-13	1	OmniActive	Direct and/or Indirect
9,226,940 (Roberts) Accused Ocular Antioxidant Products	1-13	1	OmniActive	Direct and/or Indirect

57. Further discovery may reveal that other products manufactured, sold for importation into the United States, imported into the United States, and/or sold after importation within the United States by Proposed Respondents infringe the claims of the Asserted Patents. Further discovery may also reveal that additional claims of the Asserted Patents are infringed by Proposed Respondents' products.

VII. THE DOMESTIC INDUSTRY

58. A domestic industry exists in the United States as required by 19 U.S.C. § 1337 (a)(3)(A), (B) and (C) because Complainants have made (1) significant investment within the United States in plant and equipment and (2) significant employment within the United States of labor or capital, including engineering, manufacturing, and research and development. Specific non-limiting examples of such investments are provided below.

A. Technical Prong – Complainants’ Articles Practice at Least One Claim of Each of the Asserted Patents in the United States

59. Kemin Foods manufactures and sells within the United States nutritional supplements comprising lutein and zeaxanthin. Specifically, Kemin Foods makes and sells a product sold under the trade name FloraGLO®. FloraGLO® is manufactured in Complainants’ plant in Des Moines, Iowa, and is sold throughout the United States as a component of other products, including Opti-Vue, sold by the Vitamin Shoppe. Kemin Foods further engages in a marketing campaign throughout the United States, encouraging the use of FloraGLO® to prevent eye damage due to blue and ultraviolet light.

60. Claim charts demonstrating how Kemin Foods’ current FloraGLO® products (including lutein and zeaxanthin) are covered by a claim of the ’955 and ’940 patent are attached as Exhibits 15 and 16. As these products practice at least one claim of each of the ’955 patent and ’940 patent, they satisfy the requirements of 19 U.S.C. § 1337(a)(B)(ii).

B. Economic Prong – Complainants’ Substantial Investment in the Relevant Industry, Including Manufacturing, Engineering, and Research and Development, Within the United States

61. Complainants have made significant investments in plant, equipment, labor and capital in the United States with respect to the Asserted Patents in the form of capital assets, plant and equipment, manufacturing, and labor.

62. Complainants continue to invest heavily in research and development and manufacturing in the United States. Complainants' investments in plant, equipment, labor, and capital dedicated to research and development and manufacturing related to the technology in the patents-at-issue, as well as revenues resulting from these investments, are detailed in the attached declaration. See Ex. 7C [Rich Heil Declaration].

VIII. HARMONIZED TARIFF SCHEDULE INFORMATION

63. On information and belief, the articles subject to this Complaint are classified under at least the following headings and subheadings of the Harmonized Tariff Schedule ("HTS") of the United States: 130219 (including, but not limited to subheading 420100), 330190, 121190, and 091030. These HTS numbers are illustrative only and are not intended to restrict the scope of this investigation.

IX. RELATED LITIGATION

64. The Asserted Patents are the subject of a Civil Action in the United States District Court for the District of New Jersey, filed on August 15, 2016, by OmniActive USA, naming Kemin Industries as a Defendant. *OmniActive Health Technologies, Inc. v. Kemin Industries, Inc.*, 2016-cv-04988-CCC-JBC (D.N.J. filed August 15, 2016). The action is pending.

65. Kemin Foods and OmniActive Health Technologies, Inc. have also been involved in prior litigation on unrelated patents. *Kemin Foods, L.C. et al v. OmniActive Health Technologies, Inc.*, 8:07-cv-01308-VMC-TGW (M.D. Fla. filed July 25, 2007).

66. On information and belief, the Asserted Patents have not been the subject of any other court or agency litigation, domestic or foreign.

X. RELIEF REQUESTED

WHEREFORE, by reason of the foregoing, Complainants respectfully request that the United States International Trade Commission:

- (a) institute an immediate investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, into the violations by Proposed Respondents of Section 337 arising from the importation into the United States, and/or sale for importation, and/or sale within the United States after importation, of Proposed Respondents' products that infringe at least one claim of each of U.S. Patent Nos. 8,815,955 and 9,226,940;
- (b) schedule and conduct a hearing, pursuant to 19 U.S.C. § 1337(c), for purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337 of the Tariff Act of 1930, as amended; and, following the hearing, determine that there has been a violation of Section 337 of the Tariff Act of 1930, as amended;
- (c) issue a limited exclusion order, pursuant to 19 U.S.C. § 1337(d)(1), excluding from entry for consumption into the United States, entry for consumption from a foreign trade-zone, or withdrawal from a warehouse for consumption, supplements and vitamins, including ocular antioxidants and components thereof and products containing the same, that infringe at least one claim of each of U.S. Patent Nos. 8,815,955 and/or 9,226,940 and which are manufactured by or on behalf of, or imported by or on

behalf of Proposed Respondents, or any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns, for the remaining terms of the Asserted Patents, except under license of Complainants or as provided by law;

- (d) issue permanent cease-and-desist orders, pursuant to 19 U.S.C. § 1337(f), directing Proposed Respondents and any of their principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) or majority-owned business entities, successors, and assigns, from either directly engaging in or for, with, or otherwise on behalf of Proposed Respondents, (A) importing or selling for importation into the United States supplements or food ingredients, the use of which infringe at least one claim of each of U.S. Patent Nos. 8,815,955 and/or 9,226,940; (B) marketing, distributing, offering for sale, selling, or otherwise transferring, in the United States imported supplements or food ingredients, the use of which infringe at least one claim of each of U.S. Patent Nos. 8,815,955 and/or 9,226,940; (C) advertising imported supplements or food ingredients in the United States, the use of which infringe at least one claim of each of U.S. Patent Nos. 8,815,955 and/or 9,226,940; (D) soliciting U.S. agents or distributors for supplements or food ingredients, the use of which infringe at least one claim of each of U.S. Patent Nos. 8,815,955 and/or 9,226,940; or (E) aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer, or distribution of supplements or food

ingredients, the use of which infringe at least one claim of each of U.S.

Patent Nos. 8,815,955 and/or 9,226,940;

- (e) issue a bond upon importation of infringing food supplements and vitamins including ocular antioxidants and components thereof and products containing the same, during the 60-day Presidential review period pursuant to 19 U.S.C. § 1337(e), (f), and (j); and
- (f) grant all such other and further relief as the Commission has authority to grant and deems appropriate under the law, based upon the facts complained of herein and as determined by the Investigation.

Dated: October 6, 2016

Respectfully submitted,



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