

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

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BAUSCH & LOMB INCORPORATED & :
WYETH LLC)
:
)
Plaintiffs, :
) Civil Action No. 13-CV-06498-JWF
v. :
)
VITAMIN HEALTH, INC. : JURY TRIAL DEMANDED
)
Defendant. :
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SECOND AMENDED COMPLAINT

For its Second Amended Complaint herein, Bausch & Lomb Incorporated alleges that:

NATURE OF ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, including 35 U.S.C. § 271, and for false advertising and unfair competition in violation of Section 43(a) of the Lanham Act, including 15 U.S.C. § 1125(a).

JURISDICTION AND VENUE

- 2. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and (b).
- 3. Venue is properly laid in this Court under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).
- 4. The defendant is subject to personal jurisdiction in this district.

THE PARTIES

5. Plaintiff, Bausch & Lomb Incorporated (“Bausch & Lomb”) is a corporation of the State of New York with offices at 1400 North Goodman Street, Rochester, NY 14609, within this district.

6. Plaintiff, Wyeth LLC (“Wyeth”) is a limited liability company organized and existing under the laws of Delaware and having a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

7. Defendant, Vitamin Health, Inc. (“Vitamin Health”) is a corporation of the State of Michigan with principal offices at 31800 Northwestern Highway 202, Farmington Hills, Michigan 48334. On information and belief, Vitamin Health is doing business within this district.

CLAIMS FOR RELIEF

COUNT 1: PATENT INFRINGEMENT OF U.S. PATENT NO. 6,660,297

8. Bausch & Lomb is a joint owner and licensee of all rights in the field of ophthalmology, including the right to enforce, of United States Patent No. 6,660,297 (“the ’297 Patent”) which was duly and lawfully granted on December 9, 2003 to Stephen P. Bartels, Cara L. Baustian, George E. Bunce, Leon Ellenbogen, Frederick L. Ferris III, Jin Kinoshita, James C. Smith and David A. Souerwine for an invention in “Nutritional Supplement to Treat Macular Degeneration.” Wyeth is a joint owner of the ’297 Patent. Pursuant to 35 U.S.C. § 207(a) and the exclusive license received from the U.S. government joint owner, including the right to enforce the ’297 Patent, Bausch & Lomb can maintain this action without the U.S. government as a party. A true copy of the ’297 Patent is attached as Exhibit A.

9. The '297 Patent describes and claims, among other things, methods and compositions useful as nutritional supplements for prevention, stabilization and/or treatment of visual acuity loss by reducing the risk of age-related macular degeneration and cataracts and for maintaining and preserving eye health and vision. The invention of the '297 Patent provides, *inter alia*, a formulation dosage of vitamin A in the form of beta-carotene (substituted or supplemented with lutein, zeaxanthine or a combination thereof), vitamin C, and vitamin E, as well as zinc and copper.

10. On or about September 10, 2007, a request for an *inter partes* reexamination of the '297 Patent was filed in the United States Patent and Trademark Office ("PTO"). On or about April 30, 2013, the PTO issued an *Inter Partes* Reexamination Certificate wherein the PTO determined: (1) claims 1-4, 10, 18 and 19 of the '297 Patent were patentable as amended; (2) claims 5, 6, 8, 9, 11, 12 and 14-17 of the '297 Patent were patentable and (3) new claims 22 through 32 were patentable. A true copy of the *Inter Partes* Reexamination Certificate for the '297 Patent is attached as Exhibit B.

11. Bausch & Lomb markets and sells products covered by the '297 patent within this district and elsewhere in the United States, including but not limited to PreserVision® Eye Vitamin AREDS and AREDS 2 Formula products, with notice to the public that such products are patented by affixing to the package of those products a label identifying the '297 patent.

12. Vitamin Health is infringing, inducing infringement of, and/or contributing to the infringement of the '297 Patent by making, using, offering to sell, selling, or importing, within this district or elsewhere in the United States, composition or methods covered by the '297 Patent and/or by selling, offering for sale and/or importing compositions with

instructions for use or promotions that cause and induce the user to infringe the claims in the '297 Patent, and/or by selling, offering to sell or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '297 Patent.

13. Vitamin Health is making, using, importing, offering to sell or selling, compositions containing a formulation of vitamins C and E, zinc, copper, vitamin A in the form of beta-carotene and/or lutein and zeaxanthine, that are specifically described and claimed in the '297 Patent, including but not limited to Vitamin Health's Viteyes® AREDS and AREDS 2 products. Vitamin Health is making, using, importing, offering to sell or selling, such compositions for the use in treating or preventing age-related eye disease or for maintaining or preserving eye health or vision, which infringe the claims of the '297 Patent.

14. On information and belief, Vitamin Health is selling, offering for sale and/or importing compositions with instructions for use and promotions that cause and induce the user to infringe the claims in the '297 Patent, including but not limited to Vitamin Health's Viteyes® AREDS and AREDS 2 products.

15. On information and belief, Vitamin Health is selling, offering for sale or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '297 Patent.

16. On information and belief, Vitamin Health became aware of the '297 Patent on or after its issuance date of December 9, 2003. On information and belief, Vitamin Health has willfully infringed the patent by continuing to make, use, offer for sale or import Vitamin Health's Viteyes® AREDS and AREDS 2 products.

17. Vitamin Health is on notice that Bausch & Lomb's own products, including but not limited to PreserVision® Eye Vitamin AREDS and AREDS 2 Formula, are proprietary.

18. The aforesaid sales and acts by Vitamin Health are without right, license or permission from Bausch & Lomb.

19. On information and belief, Vitamin Health intends to continue the sales and acts referred to in paragraphs 12-18.

20. Bausch & Lomb has been damaged by Vitamin Health's infringement of the '297 Patent, and will be irreparably damaged if that infringement is not enjoined.

COUNT 2: PATENT INFRINGEMENT OF U.S. PATENT NO. 8,603,522

21. Bausch & Lomb incorporates herein and realleges as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 7 above.

22. Bausch & Lomb is a joint owner and licensee of all rights in the field of ophthalmology, including the right to enforce, of United States Patent No. 8,603,522 ("the '522 Patent") which was duly and lawfully granted on December 10, 2013 to Stephen P. Bartels, Cara L. Baustian, George E. Bunce, Leon Ellenbogen, Frederick L. Ferris III, Jin Kinoshita, James C. Smith and David A. Souerwine for an invention in "Nutritional Supplement to Treat Macular Degeneration." Wyeth is a joint owner of the '522 Patent. Pursuant to 35 U.S.C. § 207(a) and the exclusive license received from the U.S. government joint owner, including the right to enforce the '522 Patent, Bausch & Lomb can maintain this action without the U.S. government as a party. A true copy of the '522 Patent is attached as Exhibit C.

23. The '522 Patent describes and claims, among other things, methods for stabilization and/or treatment of visual acuity loss by reducing the risk of age-related macular degeneration and cataracts and for maintaining and preserving eye health and vision. The invention of the '522 Patent provides, *inter alia*, a method of administering a formulation of lutein-zeaxanthine combination or vitamin A in the form of beta-carotene (substituted or supplemented with lutein, zeaxanthine or a combination thereof), vitamin C, and vitamin E, as well as zinc and copper.

24. Bausch & Lomb markets and sells products for the methods covered by the '522 Patent within this district and elsewhere in the United States, including but not limited to PreserVision® Eye Vitamin AREDS and AREDS 2 Formula products.

25. Vitamin Health is infringing, inducing infringement of, and/or contributing to the infringement of the '522 Patent by making, using, offering to sell, selling, or importing, within this district or elsewhere in the United States, products for the methods covered by the '522 Patent and/or by selling, offering for sale and/or importing compositions with instructions for use or promotions that cause and induce the user to infringe the claims in the '522 Patent, and/or by selling, offering to sell or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '522 Patent.

26. Vitamin Health is making, using, importing, offering to sell or selling, compositions containing a formulation of vitamins C and E, zinc, copper, vitamin A in the form of beta-carotene and/or lutein and zeaxanthine, that are specifically described and claimed in the '522 Patent, including but not limited to Vitamin Health's Viteyes® AREDS and AREDS 2 products. Vitamin Health is making, using, importing, offering to sell or selling, such

compositions for the use in treating or preventing age- related eye disease or for maintaining or preserving eye health or vision, which infringe the claims of the '522 Patent.

27. On information and belief, Vitamin Health is selling, offering for sale and/or importing compositions with instructions for use and promotions that cause and induce the user to infringe the claims in the '522 Patent, including but not limited to Vitamin Health's Viteyes® AREDS and AREDS 2 products.

28. On information and belief, Vitamin Health is selling, offering for sale or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '522 Patent.

29. On information and belief, Vitamin Health became aware of the '522 Patent on or after its issuance date of December 10, 2013. On information and belief, Vitamin Health has willfully infringed the patent by continuing to make, use, offer for sale or import Vitamin Health's Viteyes® AREDS and AREDS 2 products.

30. The aforesaid sales and acts by Vitamin Health are without right, license or permission from Bausch & Lomb.

31. On information and belief, Vitamin Health intends to continue the sales and acts referred to in paragraphs 25-30.

32. Bausch & Lomb has been damaged by Vitamin Health's infringement of the '522 Patent, and will be irreparably damaged if that infringement is not enjoined.

COUNT 3: FALSE ADVERTISING

33. Bausch & Lomb incorporates herein and realleges, as if fully set forth in the Paragraph, the allegations of Paragraphs 1-5 and 7 above.

34. This cause of action arises out of Defendant's knowing and willful false and misleading labeling of its products. Defendants actions constitute false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(b). Bausch & Lomb seeks permanent injunctive relief, actual damages, punitive damages, and recovery of Bausch & Lomb's costs and reasonable attorneys' fees incurred in connection with this action.

35. Age-related macular degeneration ("AMD") is the leading cause of blindness in the developed world and accounts for more than 50% of all blindness in the United States. In 2001, the National Eye Institute (NEI) of the National Institutes of Health, completed a ten-year study, the Age-Related Eye Disease Study (AREDS), demonstrating that a daily oral supplementation comprising vitamin C, vitamin E, Vitamin A in the form of beta-carotene, zinc, and copper reduced the risk of developing AMD by about 25% at 5 years.

36. In 2013, the second Age-Related Eye Disease Study (AREDS 2) was completed which tested whether adding lutein and zeaxanthin, the omega-3 fatty acids DHA and EPA, or a combination of both to the AREDS formulation might further reduce the risk of progression to advanced AMD. A secondary goal was to test the effects of eliminating beta-carotene and reducing zinc dose in the AREDS formulation. Based on the results of the AREDS 2 study, in 2013 the NEI recommended that the AREDS formula be adjusted by the removal of beta-carotene and the addition of lutein and zeaxanthin. The AREDS 2 researchers did not recommend that the amount of 80 mg of zinc proven effective in the AREDS study should be reduced based on the results of the AREDS 2 study. The results and conclusions were published as "Lutein + Zeaxanthin and Omega-3 Fatty Acids for Age-Related Macular Degeneration: The Age-Related Eye Disease Study 2 (AREDS 2) Randomized Clinical Trial," Chew *et al.*, *J. Amer. Med. Assoc.* 309(19):2005-2015 (May 15, 2013).

37. After the AREDS 2 results were announced, Vitamin Health's marketing materials represented the "AREDS2 Recommended Formula" to comprise vitamin C (500 mg), Vitamin E (400 IU), lutein (10 mg), zeaxanthine (2 mg), zinc (80 mg), and copper (2 mg). Vitamin Health marketed and sold products containing the AREDS 2 recommended formula, including Viteyes® AREDS 2, Viteyes® AREDS 2 Advanced, and Viteyes® AREDS 2 Plus Omega-3 (the "Viteyes® AREDS 2 products").

38. After Bausch & Lomb filed its original Complaint, Vitamin Health purported to change the formulation of its AREDS 2 products to contain 25 mg of zinc, rather than the AREDS 2 recommended formula containing 80 mg of zinc. These products purportedly containing 25 mg of zinc include Viteyes® AREDS 2, Viteyes® AREDS 2 Advanced, Viteyes® AREDS 2 Plus Omega-3 and Viteyes® AREDS 2 Powder (the "Viteyes® AREDS 2 25 mg zinc products")

39. On information and belief, despite no longer containing the AREDS 2 recommended 80 mg of zinc, Vitamin Health markets Vitamin Health's Viteyes® AREDS 2 25 mg zinc products with the term "AREDS 2" prominently displayed on their labels.

40. On information and belief, Vitamin Health markets and promotes the Viteyes® AREDS 2 25 mg zinc products as based on the results of the AREDS 2 study carried out by the National Institutes of Health. The 2013 *JAMA* journal article by Dr. Chew *et al.*, discussed above in Paragraph 35, is cited on the Viteyes® website as source material for its claims.

41. Vitamin Health's labeling, promotion and marketing of its Viteyes® AREDS 2 25 mg zinc products as the AREDS 2-recommended formulations are false and/or likely to mislead or confuse consumers.

42. Vitamin Health's Viteyes® AREDS 2 25 mg zinc products are marketed as competing products to Bausch & Lomb's PreserVision® products. The distribution and sale of the Viteyes® AREDS 2 25 mg zinc products has caused and will continue to cause Bausch & Lomb to lose sales of its PreserVision® AREDS 2 products, to both existing and future Bausch & Lomb customers.

43. Vitamin Health's marketing and promotional statements for its Viteyes® AREDS 2 25 mg zinc products, stating that these products are based on the recommendations made by NEI researchers following the results of the AREDS 2 study, are materially false statements that are likely to cause consumer confusion, mistake, or deception as to the quality and content of the Viteyes® AREDS 2 25 mg products. These are material misrepresentations upon which customers or potential customers have relied, and will rely. Vitamin Health's actions therefore mislead and harm customers and consumers in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

44. Upon information and belief, Vitamin Health's acts were undertaken willfully and deliberately and with the intention of causing confusion, mistake, or deception.

45. The aforesaid acts by Vitamin Health have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Bausch & Lomb for which Bausch & Lomb has no adequate remedy at law.

PRAYER FOR RELIEF

46. WHEREFORE, Plaintiff Bausch & Lomb respectfully requests the following relief:

A. A judgment and decree that United States Patent No. 6,660,297 remains valid and enforceable;

B. A judgment that Vitamin Health, Inc. has infringed one or more claims of Bausch & Lomb's United States Patent No. 6,660,297;

C. A judgment that Vitamin Health, Inc. has induced infringement of one or more claims of Bausch & Lomb's United States Patent No. 6,660,297;

D. A judgment that Vitamin Health, Inc. has contributed to the infringement of one or more claims of Bausch & Lomb's United States Patent No. 6,660,297;

E. A judgment that Vitamin Health, Inc. has willfully infringed one or more claims of Bausch & Lomb's United States Patent No. 6,660,297.

F. A judgment and decree that United States Patent No. 8,603,522 remains valid and enforceable;

G. A judgment that Vitamin Health, Inc. has infringed one or more claims of Bausch & Lomb's United States Patent No. 8,603,522;

H. A judgment that Vitamin Health, Inc. has induced infringement of one or more claims of Bausch & Lomb's United States Patent No. 8,603,522;

I. A judgment that Vitamin Health, Inc. has contributed to the infringement of one or more claims of Bausch & Lomb's United States Patent No. 8,603,522;

J. A judgment that Vitamin Health, Inc. has willfully infringed one or more claims of Bausch & Lomb's United States Patent No. 8,603,522.

K. A permanent injunction restraining and enjoining Vitamin Health, Inc., its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions and methods claimed in Bausch & Lomb's United States Patent Nos. 6,660,297 and 8,603,522 or components or materials especially made or especially adapted for use in an infringement of Bausch & Lomb's United States Patent Nos. 6,660,297 and 8,603,522;

L. An accounting of all damages to Bausch & Lomb arising from Vitamin Health, Inc.'s infringement, inducement of infringement, contributory infringement and willful infringement, and that such damages be awarded to Bausch & Lomb together with interest;

M. A judgment and decree that Vitamin Health, as a result of its willful, deliberate, and materially false statements regarding the quality and content of its products, has engaged in false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(b);

N. A permanent injunction ordering Vitamin Health to, *inter alia*, immediately cease all distribution and sale of the Viteyes® AREDS 2 25 mg zinc products;

O. An order that Vitamin Health recall all of the Viteyes® AREDS 2 25 mg zinc products currently in the marketplace;

P. An order that Vitamin Health engage in a program of corrective advertising, satisfactory to Bausch & Lomb, to ameliorate the false and misleading information that Vitamin Health has promulgated;

Q. An award of damages in an amount sufficient to compensate Bausch & Lomb for injury it has sustained as a consequence of Vitamin Health's unlawful false advertising and unfair competition;

R. An award of treble damages;

S. An award of punitive damages in an amount sufficient to punish and deter Vitamin Health from engaging in further knowing acts of false advertising;

T. A grant of the costs of this action and reasonable attorneys' fees incurred by Bausch & Lomb in connection with this action; and

U. Such other and further relief as the Court may deem just and proper.

June 10, 2014

Respectfully submitted,

s/ Joshua A. Davis

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