

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

BAUSCH & LOMB INCORPORATED &)	
PF CONSUMER HEALTHCARE 1 LLC,)	
)	
Plaintiffs,)	
)	C.A. No. 20-CV-6447
v.)	
)	
LUNOVUS LLC,)	
)	JURY TRIAL DEMANDED
Defendant.)	
)	

COMPLAINT

Plaintiffs Bausch & Lomb Incorporated (“Bausch & Lomb”) and PF Consumer Healthcare 1 LLC (“PF Consumer Healthcare 1”) (collectively, “Plaintiffs”), by their attorneys, hereby allege as follows:

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.

THE PARTIES

2. Plaintiff Bausch & Lomb is a corporation organized and existing under the laws of New York, with a place of business at 1400 North Goodman Street, Rochester, NY 14609, within this district.

3. Plaintiff PF Consumer Healthcare 1 is a limited liability company organized and existing under the laws of Delaware and having a place of business at 1209 Orange Street, Corporation Trust Center, Wilmington, DE, 19801.

4. Defendant Lunovus LLC (“Lunovus”) is a limited liability company organized and existing under the laws of Alabama and with a principal place of business at 729 1st Ave. N., Birmingham, AL 35203. On information and belief, Lunovus is doing business within this district.

JURISDICTION AND VENUE

5. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and (b).

6. This Court has personal jurisdiction over Lunovus. On information and belief, Lunovus, directly or through its alter ego, affiliates, or agents, develops, formulates, manufactures, markets, and sells vitamin products throughout the United States, including in New York and this judicial district. On information and belief, Lunovus regularly conducts and solicits business in the State of New York, engages in other persistent courses of conduct in the State of New York, and/or derives substantial revenue from services or things used or consumed in the State of New York. On information and belief, Lunovus transacts business within the State of New York related to Bausch & Lomb’s claims, and has engaged in systematic, pervasive, and continuous business contacts within the State of New York and this judicial district.

7. On information and belief, venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

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.” PF Consumer Healthcare 1 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 its PreserVision[®] 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. Lunovus 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, compositions 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. Lunovus is making, using, importing, offering to sell, or selling compositions containing a formulation of lutein, zeaxanthin, vitamins C and E, zinc, and copper, that are specifically described and claimed in the '297 Patent, including but not limited to Lunovus' Visual Advantage AREDS 2 product. Lunovus 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, Lunovus 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 Lunovus' Visual Advantage AREDS 2 product.

15. On information and belief, Lunovus is selling, offering for sale and/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, Lunovus became aware of the '297 Patent on or after its issuance date of December 9, 2003. On information and belief, Lunovus has willfully infringed the patent by continuing to make, use, offer for sale, sell, or import Lunovus' Visual Advantage AREDS 2 product.

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

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

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

20. Bausch & Lomb has been damaged by Lunovus' 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." PF Consumer Healthcare 1 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 its PreserVision[®] AREDS and AREDS 2 Formula products.

25. Lunovus 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. Lunovus is making, using, importing, offering to sell, or selling compositions containing a formulation of lutein, zeaxanthin, vitamins C and E, zinc, and copper, that are specifically described and claimed in the '522 Patent, including but not limited to Lunovus' Visual Advantage AREDS 2 product. Lunovus 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, Lunovus 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 Lunovus' Visual Advantage AREDS 2 product.

28. On information and belief, Lunovus is selling, offering for sale and/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, Lunovus became aware of the '522 Patent on or after its issuance date of December 10, 2013. On information and belief, Lunovus has willfully infringed the patent by continuing to make, use, offer for sale, sell, or import Lunovus' Visual Advantage AREDS 2 product.

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

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

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

PRAYER FOR RELIEF

33. 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 Lunovus has infringed one or more claims of Bausch & Lomb's United States Patent No. 6,660,297;

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

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

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

I. A judgment that Lunovus 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 Lunovus 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 Lunovus, 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 Lunovus' infringement, inducement of infringement, contributory infringement and willful infringement, and that such damages be awarded to Bausch & Lomb together with interest;

M. A permanent injunction ordering Lunovus to, *inter alia*, immediately cease all distribution and sale of the Visual Advantage AREDS 2 product;

N. An order that Lunovus recall all of the Visual Advantage AREDS 2 products currently in the marketplace;

O. An award of treble damages;

P. A grant of the costs of this action and reasonable attorneys' fees incurred by Bausch & Lomb in connection with this action; and

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

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