

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

HOWARD FOUNDATION HOLDINGS)	
LIMITED,)	
)	
Plaintiff,)	
)	C.A. No. 12-35-RGA
v.)	
)	JURY TRIAL DEMANDED
INTERNATIONAL VITAMIN CORPORATION,)	
)	
Defendant.)	

FIRST AMENDED COMPLAINT

Plaintiff Howard Foundation Holdings Limited (“HFH”), for its First Amended Complaint against defendant International Vitamin Corporation (IVC”), alleges as follows:

PARTIES

1. HFH is a United Kingdom public limited company with its principal place of business located in Leeds, United Kingdom.

2. IVC is a Delaware corporation with its principal place of business located at 500 Halls Mill Road, Freehold, New Jersey.

JURISDICTION AND VENUE

3. This is an action for patent infringement arising from Title 35 of the United States Code, 35 U.S.C. §§ 1 *et seq.*

4. Exclusive jurisdiction over this matter is conferred upon the Court pursuant to 28 U.S.C. §§ 1331, 1338.

5. The exercise of personal jurisdiction over the defendant comports with the laws of this State and the constitutional requirements of due process because the defendants transact business and/or offer to transact business within this State. IVS’ products and services are offered to and may be purchased and/or used by citizens of Delaware.

6. Venue is proper in this District under 28 U.S.C. §§ 1391, 1400(b).

FACTS

7. The Howard Foundation (“Foundation”), a United Kingdom charitable trust located in Cambridge, United Kingdom, owns the entire right, title and interest to U.S. Patent No. 6,329,432 (“the ‘432 patent”), which issued on or about December 11, 2001 and is entitled “Mesozeaxanthin formulations for treatment of retinal disorders”. The inventors of the ‘432 patent are Alan Norman Howard, John T. Landrum, and Richard A. Bone. A true and correct copy of the ‘432 patent is attached as Exhibit 1 and incorporated by reference.

8. Founded in 1982, the aims of the Foundation include providing funding for biomedical research in the fields of obesity and nutrition and research into the means of relieving malnutrition, especially in undeveloped countries.

9. The Foundation has exclusively licensed the ‘432 patent to HFH, which is engaged in the business of licensing patents and the sale of nutraceutical products. HFH holds all substantial rights to the ‘432 patent and it has standing to sue third parties for infringement.

10. HFH’s authorized distributor of licensed products maintains a website that marks the products with the ‘432 patent and other patents. <http://www.eyecarotenoids.com/patents.html> (Exhibit 4).

11. IVC manufactures vitamin and nutritional supplement products, including various private label brands. IVC owns, maintains and operates a website at <http://www.ivcinc.com>, the content of which is incorporated herein by reference.

12. IVC makes tablets, caplets, soft gels, chewable tablets and two-piece capsules for various nutritional categories. IVC represents that it “services thousands of retail stores in the food, chain drug, mass merchandise, warehouse club and natural products channels. We produce

hundreds of formulas and distribute thousands of SKUs for retailers in North America and throughout the world.” (Exhibit 5).

13. IVC manufactures, uses, offers for sale and sells products that contain a carotenoid called Mesozeaxanthin (“the infringing products”). The infringing products include without limitation one made, used, offered for sale and sold as trunature[®] Lutein and Zeaxanthin.

14. An independent testing laboratory confirmed that IVC’s trunature[®] Lutein and Zeaxanthin product contains material quantities of Mesozeaxanthin. A true and correct copy of an Analytical Laboratory Report by Industrial Organica, S.A. de C.V. is attached as Exhibit 2 and incorporated herein by reference.

15. IVC’s product advertises and represents to the public that its products containing Mesozeaxanthin are “clinically proven for healthy vision”, as shown by the following example of its product packaging:



A true and correct copy of additional product packaging material is attached as Exhibit 3 and incorporated herein by reference.

16. IVC purchases the Mesozeaxanthin included as a component of its infringing products from OmniActive Health Technologies, Ltd. (“OmniActive”), a company headquartered in India, sold under the brand name Lutemax 2020[™]. The label for the infringing

products includes the Lutemax 2020 logo and represents that: “trunature[®] Lutein and Zeaxanthin is made with Lutemax 2020[™], a premium ingredient that provides the optimal balance of both Lutein and Zeaxanthin. Patent Pending.” (Exhibit 3). The “Patent Pending” refers to an application by T.K. Kumar, *et al.*, Application No. 12/874,636, entitled Xanthophyll Composition Containing Macular Pigments And A Process For Its Preparation (“the ‘636 application”). The ‘636 application was filed on September 10, 2010, published by the U.S. Patent and Trademark Office (“USPTO”) on March 17, 2011 (Pub. No. 2011/0065805), and listed OmniActive as the assignee. A true and correct copy of the published application is attached as Exhibit 6. The ‘636 patent remains pending.

17. Significantly, the specification for the ‘636 application specifically refers to the patent-in-suit here:

As already mentioned earlier, the dietary source of meso-zeaxanthin is mainly from seafoods like shrimps, fish, turtle, etc, thereby the vegetarian population is deprived of meso-zeaxanthin. However, there is a patent available for pharmaceutical composition containing meso-zeaxanthin for the treatment of retinal disorders like increasing the deposition of macular pigments in the human eye and therapeutic treatment or prophylaxis of AMD (**Howard et al., Meso-zeaxanthin Formulations for Treatment of Retinal Disorders, U.S. Pat. No. 6,329,432, 2001**). [Exhibit 6, ¶ 0023, emphasis added.]

Thus, the ‘636 application indicates the patent-in-suit exists and indicates the patent covers meso-zeaxanthin for eye health.

18. Under the heading “Prior Art”, the specification of the ‘636 application again refers to the ‘432 patent for increasing meso-zeaxanthin in the eye:

In addition, there are pharmaceutical formulations containing (R,S)-zeaxanthin for increasing macular pigment density in the human eye and for therapeutic treatment or prophylaxis of diseases and disorders of macula. (Howard et. al., Meso-zeaxanthin Formulations for Treatment of Retinal Disorders, U.S. Pat. No. 6,379,432, 2001). [*Id.* ¶ 0029.]

19. The Information Disclosure Statement (“IDS”) filed by OmniActive with the USPTO on March 25, 2011 as part of the ‘636 application’s prosecution history also expressly lists the ‘432 patent. A true and correct copy of this IDS is attached as Exhibit 7.

20. In addition, OmniActive is the assignee of another application by T.K. Kumar, *et al.*, Application No. 11/800,317, entitled Novel Xanthophyll Composition Containing Trans, Meso-Zeaxanthin, Trans, R, R-Zeaxanthin and Trans, R, R-Lutein Useful for Nutrition and Health Care and a Process for Its Preparation (“the ‘317 application”). The ‘317 application was filed on May 4, 2007, and published by the USPTO on November 15, 2007 (Pub. No. 2007/0265351). An IDS filed by OmniActive with the USPTO on July 20, 2007 as part of the ‘317 application’s prosecution history expressly lists the ‘432 patent. A true and correct copy of the IDS is attached as Exhibit 8. The ‘317 application remains pending; the USPTO mailed a notice of allowance and fees due on February 23, 2012.

21. At the time IVC marked its product with the “Patent Pending” designation referring to OmniActive’s applications, it had actual knowledge of the contents of that application and the existence of the ‘432 patent. False patent marking is a violation of 35 U.S.C. § 292.

22. In or around 2007, HFH’s representative had discussions with one or more employees of Leiner Health Products Inc. (“Leiner”), substantially all the assets of which were purchased by NBTY, Inc. in July 2008. Those 2007 discussions included HFH’s ‘432 patent. One or more Leiner employees with knowledge of the ‘432 patent later became employees of IVC. The knowledge of its employee(s) is imputed to IVC. IVC had actual knowledge of the ‘432 patent before this suit was filed but it continued to infringe that patent.

23. By letter dated November 18, 2010 to Sanjaya Mariwala, HFH's counsel gave actual knowledge of the '432 patent to OmniActive in connection with the Lutemax 2020™ product. HFH and OmniActive subsequently had discussions regarding the '432 patent. On information and belief, OmniActive informed its customer, IVC, of HFH's communication of that patent. Indeed, after this suit was filed, on or about January 17, 2012, HFH sent a copy of the as yet unserved complaint to IVC's President and CEO. On or about January 20, 2012, OmniActive's counsel contacted HFH's counsel to discuss the lawsuit against IVC.

24. IVC's infringing products are sold by Costco Wholesale Corp. through retail stores, including one in Delaware.

25. IVC's infringing products also are offered for sale and sold and may be ordered from Costco's website, www.costco.com. Costco's website represents that:

As we age, our bodies cannot restore Lutein and Zeaxanthin in the macula, therefore daily supplementation is necessary. Taking trunature® Lutein and Zeaxanthin helps to replace these powerful antioxidants, which may help support healthy eyes and vision.

Lutein and Zeaxanthin are carotenoids found in vegetables and fruits. They act as antioxidants, protecting cells against the damaging effects of free radicals and help support healthy eyes and vision. The normal diet delivers a 5:1 ratio of Lutein and Zeaxanthin to the body. Our product contains Lutemax™ 20/20 which matches that normal balance.

Lutein and Zeaxanthin are naturally found in the macula of the eye.

These carotenoids are clinically proven for healthy vision.

May act as a filter from potentially damaging ultra-violet light.

Powerful antioxidants.

May help improve visual acuity. [Footnote omitted.]

26. IVC's infringing product also are offered for sale and sold and may be ordered from Amazon.com, Inc. *See* Exhibit 3.

27. A May 12, 2012 article entitled Dietary Supplements and Eye Health Ingredients in Nutritional Outlook stated that:

One commercially available combination of carotenoids, Lutemax 2020 from OmniActive Health Technologies (Short Hills, NJ), provides two nutritionally relevant isomers of zeaxanthin—3R, 3'R zeaxanthin and meso-zeaxanthin—in addition to lutein. According to Hiren Doshi, vice president of OmniActive, "These isomers are critical players in fighting the natural effects of aging and in supplying the macula with vital, protective nutrients. Together, lutein; 3R, 3'R zeaxanthin; and meso-zeaxanthin protect and support the macula of the eye for overall eye health."

<http://www.nutritionaloutlook.com/print/7243>.

28. IVC makes, imports, uses, offers for sale and sells products that fall within the scope of one or more claims of the '432 patent. In addition, IVC contributes to and induces others to infringe one or more claims of the '432 patent.

29. IVC is not licensed or authorized to use IVC's intellectual property (including the '432 patent) for all of the products they sell or methods they teach.

30. The documents referred to herein are incorporated herein by reference.

COUNT I
(Patent Infringement)

31. The foregoing allegations of this complaint are incorporated by reference.

32. IVC has made, used, sold, offered for sale and/or imported products embodying the patented invention, thereby infringing, literally or under the doctrine of equivalents, one or more claims of the '381 patent, and will continue to do so unless enjoined therefrom.

33. IVC has contributed to the use, sale and/or offer for sale by others of its infringing products, methods and services.

34. IVC has induced the use, sale and/or offer for sale by others of its infringing products, methods and services.

35. IVC's infringement has been willful. IVC knew or should have known of the '432 patent prior to the filing of this lawsuit. That patent was twice discussed in the '636 application, which constituted the basis for IVC's "Patent Pending" marking on its infringing trunature[®] products that included OmniActive's Lutemax 2020[™]. IVC's supplier, OmniActive, also had actual knowledge of the '432 patent.

36. There was a high likelihood that IVC's conduct in making, using, offering for sale and selling its product constituted infringement of the '432 patent. This risk was either known or should have been known to IVC and IVC acted recklessly and in disregard to the '432 patent in making, using, offering for sale and selling its product.

37. HFH has been irreparably harmed by IVC's acts of infringement and have suffered damages in an amount to be determined at trial.

REQUEST FOR RELIEF

HFH respectfully requests that this Court enter judgment against defendant and that the following relief be granted:

- a. judgment that defendant has infringed claims of the '381 patent (35 U.S.C. § 271);
- b. judgment that defendant's infringement of claims of the '381 patent was willful;
- f. preliminary and permanent injunction against continued infringement (35 U.S.C. § 283);
- g. damages for past infringement (35 U.S.C. § 284);
- h. increased and trebled damages for willful infringement (35 U.S.C. § 284);
- i. imposition of a constructive trust on all proceeds from the sale of accused products;
- q. attorneys' fees as allowed by law, including without limitation, 35 U.S.C. § 285;

- r. costs pursuant to Fed. R. Civ. P. 54(d) or otherwise provided by law; and
- s. such other relief as the Court deems just and appropriate under the circumstances.

JURY DEMAND

Plaintiffs hereby demand a jury trial on all issues so triable.

Respectfully submitted,

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