

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KANEKA CORPORATION,
A Japanese Corporation.

Plaintiff,

v.

DESIGNS FOR HEALTH, INC.,
A Delaware Corporation, and AMERICAN
RIVER NUTRITION LLC, A Delaware
Corporation

Defendants.

DEMAND FOR JURY TRIAL

C.A. No. _____

COMPLAINT

Plaintiff Kaneka Corporation (“Kaneka”) files this Complaint for Patent Infringement and Demand for Jury Trial against Designs For Health Inc. (“DFH”) and American River Nutrition LLC (“ARN”).

NATURE OF THE ACTION

1. This is an action for Patent infringement under the laws of the United States, Title 35, United States Code by Kaneka against DFH and ARN.
2. This action arises from DFH’s manufacture, use, offer for sale, and sale in the United States of the supplements, DuoQuinol and CoQnol (“Accused Products”) which, upon information and belief, were designed and developed by ARN, and manufactured, offered for sale and sold by DFH under the trademarks “DuoQuinol” and/or “CoQnol” These activities infringe, either literally or under the doctrine of equivalents, and induce others to infringe two Patents owned by Kaneka.

THE PARTIES

3. Kaneka is a Japanese Corporation with a head office at 1-12-32, Akasaka, Minato-Ku, Tokyo, Japan, and a head office at 2-3-18, Nakanoshima, Kita-Ku, Osaka, Japan.

4. DFH is a Delaware Corporation at 14 Commerce Blvd., Palm Coast, FL 32164. DFH may be served with process through its registered agent, Northwest Registered Agent Service Inc., 8 The Green, Ste. B, Dover, Delaware 19901.

5. ARN is a Delaware Corporation at 333 Venture Way, Hadley, MA 01035. ARN may be served through its registered agent, Northwest Registered Agent Service Inc., 8 The Green, Ste. B, Dover, Delaware, 19901.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§1331 and 1338(a).

7. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over the Defendants.

8. This Court has personal jurisdiction over DFH and ARN as both are Delaware Corporations.

9. This Court additionally has personal jurisdiction over the Defendants because upon information and belief, the Defendants have knowingly directly infringed, and induced infringement within this District by advertising, marketing and offering for sale the Accused Products within this District, to consumers, customers, distributors, resellers, partners and/or end users, and providing instructions, advertising, and/or marketing materials that facilitate, direct or encourage the use of the Accused Products.

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

Kaneka's Innovations

11. Kaneka Corporation is an international company that produces a number of different products at plants around the world. It has also been the world's premier supplier of Coenzyme Q₁₀ ("CoQ₁₀") supplements for more than 40 years. CoQ₁₀ is found in every cell of the human body. The human body makes CoQ₁₀ and the cells use it to produce energy that the human body needs for cell growth and cell maintenance. It also protects the body from damage caused by harmful molecules. CoQ₁₀ levels in the body decrease with age, which explains why millions of people take Kaneka CoQ₁₀ on a daily basis. Kaneka sells CoQ₁₀ as a nutritional supplement, similar to vitamins.

12. There are two types of CoQ₁₀. The oxidized form is known as Ubiquinone, and the reduced form is known as Ubiquinol. Kaneka was the first industrial scale manufacturer of Ubiquinone, starting in 1977. When exposed to air, reduced CoQ₁₀ (Ubiquinol) quickly undergoes a chemical reaction—oxidation—and converts to oxidized CoQ₁₀ (Ubiquinone). Kaneka was the first manufacturer in the world to succeed in the development of technology to stabilize Ubiquinol so that it did not quickly oxidize when exposed to air. Kaneka began sales of Ubiquinol in the U.S. in 2006. Kaneka has been awarded a number of patents covering its Ubiquinol products and due to that patent protection Kaneka is the only company that has the legal right to produce and sell Ubiquinol in the United States. DFH admits that the Accused Products are a form of Ubiquinol. (See Exhibit C)

13. During its 40 year history of producing CoQ₁₀ products, Kaneka has supported hundreds of CoQ₁₀ clinical research studies at universities and hospitals around the globe. Kaneka has focused its research support by working with top, independent academic research

institutions conducting research into the functionality and health benefits of all forms of CoQ₁₀ to ensure that the CoQ₁₀ products made by Kaneka are safe and effective. All CoQ₁₀ products made by Kaneka have satisfied all applicable FDA standards and other government agency requirements for safety and efficacy. Kaneka has ensured the safety and efficacy of its CoQ₁₀ products for the entire 40 year history of producing these products.

14. Over this 40 year period, Kaneka has been granted over 37 U.S. Patents covering the production of CoQ₁₀ products, and numerous CoQ₁₀ related Patents issued in other countries around the world.

The Asserted Patents

15. United States Patent No. 7,145,044 (the “’044 Patent”) titled “Method Of Producing Reduced Coenzyme Q₁₀ Using Solvent with High Oxidation-Protective Effect” was duly issued on December 5, 2006, and remains unexpired. A true and correct copy of the ’044 Patent is attached as Exhibit A and is assigned to and owned by Kaneka Corporation.

16. United States Patent No. 7,829,080 (the “’080 Patent”) titled “Stabilization Method Of Reduced Coenzyme Q₁₀” was duly issued on November 9, 2010, and remains unexpired. A true and correct copy of the ’080 Patent is attached hereto as Exhibit B and is assigned to and owned by Kaneka Corporation.

The DFH Infringing Product and Activities

17. The Accused Products are DuoQuinol and CoQnol. DFH admits that DuoQuinol is a form of Ubiquinol, derived from Ubiquinone through a process involving the use of geranygeraniol (GG) and ascorbyl palmitate. (*See* Exhibit C.) Upon information and belief, the DuoQuinol product was designed and developed by Dr. Barrie Tan, the founder of ARN. ARN then provided DFH the information required to produce DuoQuinol on a commercial scale, and

the production was done by Ashley-Martin Manufacturing, the DFH manufacturing unit.¹ DFH markets, advertises, offers for sale, and sells the Accused Products under the name CoQnol.

18. Defendant ARN has induced the direct infringement of DFH by designing and developing the DuoQuinol product and providing DFH with the information required to produce DuoQuinol on a commercial scale. Upon information and belief, Ashley-Martin Manufacturing, the DFH manufacturing unit, does not have the experience to design and develop a new type of Ubiquinol like the DuoQuinol product. A review of the employees at Ashley-Martin Manufacturing on Linked In shows a number of employees with manufacturing and production experience, but none with a research background. In contrast, Dr. Tan has a PhD in Chemistry/Biochemistry, and the ARN website states that Dr. Tan's mission "is to deliver the highest quality nutritional products based on sound scientific research." Dr. Tan is also very familiar with Kaneka Corporation. In the 2015-2016 time period, Kaneka Corporation entered into business discussions with ARN. During those discussions Dr. Tan acknowledged that he knew Kaneka very well and followed the company closely. Dr. Tan also acknowledged that he had followed the science and chemistry of CoQ10 all of his life. ARN is also very familiar with the world of patents and patent litigation, as ARN has over 13 issued patents and pending patent applications, and ARN is currently the plaintiff in a patent infringement case in the Central District of California. Accordingly, upon information and belief, ARN had the expertise to design and develop a new form of Ubiquinol, and to provide that information to DFH. As Dr.

¹ Upon information and belief, the manufacturing unit of DFH goes by the name of Ashley-Martin Manufacturing. Ashley-Martin Manufacturing LLC was initially formed in Delaware on November 6, 2006. On March 31, 2015, Ashley-Martin Manufacturing LLC merged with DFH, with DFH continuing as the surviving company.

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