

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
Limited Liability Company,

Defendants.

DEMAND FOR JURY TRIAL

C.A. No. 21-209-RGA

FIRST AMENDED COMPLAINT

Plaintiff Kaneka Corporation (“Kaneka”), for its First Amended Complaint for Patent Infringement and Demand for Jury Trial against Designs For Health Inc. (“DFH”) and American River Nutrition LLC (“ARN”), hereby allege as follows:

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”). DuoQuinol is a form of Ubiquinol that was created by Dr. Barrie Tan, the founder of ARN and the Chief Science

Officer of DFH. DFH now owns ARN. DFH directly infringes, and ARN induces DFH's direct infringement of 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 Limited Liability Company 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 as a Delaware Corporation and personal jurisdiction over ARN as a Delaware Limited Liability Company.

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 creating and producing the Accused Products and then 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. Ubiquinol is referred to herein as reduced CoQ10, reduced coenzyme Q10 or 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; *see also* ¶¶ 18-21 below.)

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 requirements 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 Products and Activities

17. The Accused Products are DuoQuinol and CoQnol. DFH admits that DuoQuinol is a form of Ubiquinol, derived from Ubiquinone. CoQnol includes DuoQuinol plus GeranyGeraniol (GG) and ascorbyl palmitate. (See Exhibit C) The DuoQuinol product was created by Dr. Barrie Tan, the founder of ARN. ARN then provided DFH the information required to produce DuoQuinol and CoQnol on a commercial scale, and the production is 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. DFH has produced and published two videos on YouTube about DuoQuinol and CoQnol. The first video was published on December 2, 2020 and can be accessed on the following link;

CoQnol- Advances in CoQ10 Supplementation
<https://carterledyard.sharefile.com/d-s4a951b59176040fd8832312c5bba022f>

19. The second video was published on January 4, 2021 and can be accessed on the following link;

CoQnol from Designs for Health
<https://carterledyard.sharefile.com/d-sa6057e6afdce4229b5aadadf26511c80>

¹ Upon information and belief, the manufacturing unit of DFH uses the name 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.

20. In the first two minutes of the first link cited in Paragraph 18, DFH claims that the DuoQuinol Ubiquinol is less expensive than Kaneka's Ubiquinol and further states:

"The reason for the price reduction is that previously there was a supplier that had a patented form of Ubiquinol that was used by lots of brands and was very expensive. Now we are able to offer our patented DuoQuinol at a much lower price since the Chief Science Officer of Designs for Health, Dr. Barrie Tan, created the DuoQuinol proprietary process. We are also the only company able to offer GG in our formulation since Dr. Tan's company, American River Nutrients, is the only producer."

21. This video presentation, and in particular the quoted portion above, verifies the following facts:

- DFH and ARN admit that DuoQuinol is a form of Ubiquinol which came from ARN (see also Ex C),
- DFH and ARN were aware that Kaneka's Ubiquinol product was patented at least as early as the date of the YouTube presentation, December 2, 2020,
- DFH and ARN admit that Dr. Barrie Tan is the Chief Science Officer of DFH and is the person who created DuoQuinol,
- ARN is the only company providing GG to DFH which DFH needs in order to sell CoQnol (which includes DuoQuinol Ubiquinol).

22. In the first two minutes of the second link cited in Paragraph 19, DFH specifically identifies Kaneka as its previous supplier of Ubiquinol when in the first link DFH only referred to "a supplier" of Ubiquinol. In the second link cited in Paragraph 19, DFH also confirms that it now owns ARN.

23. 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 has filed at least three patent infringement cases as a plaintiff. *See American River Nutrition, LLC v. Beijing Gingko Group Biological Technology Co., Ltd., et al.*, No. 8:18-CV-2201 (C.D. Cal.); *American River Nutrition, LLC v. Kyani, Inc.*, No. 2:21-CV-2613 (C.D. Cal.); *American River Nutrition, LLC v. Kyani, Inc.*, No. 4:19-CV-255 (D. Idaho). There is no dispute that DFH/ARN knew that Kaneka's Ubiquinol product was patented and that the DuoQuinol product created by Dr. Tan is a form of Ubiquinol. Accordingly, as explained in detail below, ARN and Dr. Tan have induced DFH's direct infringement of Kaneka's two patents, while knowing that Kaneka's Ubiquinol product was patented, by creating DuoQuinol, assisting DFH in the production of DuoQuinol/CoQnol as DFH's Chief Science Officer and providing DFH with the GG component that DFH needs in order to manufacture, use and sell CoQnol which includes DuoQuinol. Alternatively, if ARN did not take steps to investigate the patents knowingly held by Kaneka covering Ubiquinol products, it was unquestionably willfully blind in failing to conduct that investigation.

24. The Defendants have either induced infringement or infringed directly one or more claims of the Asserted Patents and continue to infringe (literally and under the doctrine of equivalents), directly, indirectly, and/or through agents or intermediaries by making, using, offering for sale and/or selling the Accused Products in the United States.

25. The DFH customers (including distributors and retailers) have infringed and/or continue to infringe (literally and under the doctrine of equivalents) directly, indirectly, and/or through agents or intermediaries, one or more claims of the Asserted Patents by using, offering for sale, and/or selling the Accused Product in the United States.

26. The DFH infringement has caused, is causing, and will continue to cause Kaneka to suffer damage, and Kaneka is entitled to recover damages from defendants in an amount proven at trial, but no less than a reasonable royalty as provided by 35 U.S.C. § 284.

COUNT I
(Direct Infringement of the '044 Patent by DFH)

27. Kaneka incorporates each of the preceding paragraphs as if fully set forth herein.

28. DFH has been and is now directly infringing claims 1 and 13 of the '044 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling in the United States the Accused Products that infringe the claims of the '044 Patent.

29. By way of example, claim 13 of the '044 Patent reads as follows:

“13). A reduced coenzyme Q10 crystal with a reduced coenzyme Q10 /oxidized coenzyme Q10 weight ratio of not lower 96/4”.

30. Exhibit D shows the tests done by Kaneka on the reduced Q10 ratio in the CoQnol capsules produced and sold by DFH. Exhibit D includes three separate reports labeled Analysis Report 1, Analysis Report 2 and Analysis Report 3. Table 1 in Report 1 shows that the reduced Q10 ratio was 99.7, more than the claimed requirement of not lower than 96/4. Reports 2 and 3 show that the reduced Q10 found in the CoQnol capsule is crystalized. DFH thereby directly infringes claim 13 of the '044 Patent.

31. DFH's direct infringement of Claims 1 and 13 of the '044 Patent is further detailed in the claim charts attached as Exhibit E.

32. DFH has been, and is now, indirectly infringing the '044 Patent in violation of 35 U.S.C. § 271(b) by actively inducing the direct infringement of the '044 Patent by their

distributors, retailers and customers, including at least by the distributors, retailers and customers making, using, offering for sale and/or selling the Accused Products in the United States.

33. As a consequence of DFH's infringement of the '044 Patent, Kaneka has suffered, is suffering, and will continue to suffer, damages in an amount not yet determined, but no less than a reasonable royalty.

COUNT II
(Direct Infringement of the '080 Patent by DFH)

34. Kaneka incorporates each of the preceding paragraphs as if fully set forth herein.

35. DFH has been, and is now, directly infringing claims 1, 5 and 15 of the '080 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling in the United States the Accused Products that infringe the claims of the '080 Patent.

36. By way of example, claim 5 of the '080 Patent reads as follows:

“5) A reduced coenzyme Q10-containing composition, comprising reduced coenzyme Q10 and one or both of (a) and (b): (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q9 relative to reduced coenzyme Q10, and (b) reduced coenzyme Q11, wherein not less than 0.01 wt % of reduced coenzyme Q10 is contained in the composition, and wherein the proportion of reduced coenzyme Q10 relative to the total amount of coenzyme Q10 is not less than 90 wt %.”

37. DFH produces and sells DuoQuinol/CoQnol which is reduced coenzyme Q10. Exhibit D, Report 1, are Kaneka's test results on CoQnol capsules produced and sold by DFH. The tests show in Table 1 that the proportion of reduced coenzyme Q10, relative to the total amount of coenzyme Q10 was 99.7% and Table 2 shows that 88ug of Q11 was present in the CoQnol capsule. Accordingly, DFH directly infringes claim 5 of the '080 Patent. For the same reasons, DFH also directly infringes at least claims 1 and 15 of the '080 Patent.

38. DFH's infringement of Claims 1, 5, and 15 of the '080 Patent is further detailed in Exhibit E.

39. DFH has been, and is now, indirectly infringing the '080 Patent in violation of § 271(b) by actively inducing the direct infringement of the '080 Patent by their distributors, retailers and customers, including at least by making, using, offering for sale, and/or selling the Accused Products.

40. As a consequence of DFH's infringement of the '044 Patent, Kaneka has suffered, is suffering, and will continue to suffer, damages in an amount not yet determined, but no less than a reasonable royalty.

COUNT III
(Induced Infringement by ARN of the '046 and '080 Patents)

41. Kaneka incorporates each of the proceeding paragraphs as if fully set forth herein.

42. ARN has been, and currently is, inducing infringement of the '044 and '080 Patents in violation of 35 USC § 271(b) by knowingly encouraging and aiding DFH to make, use, sell or offer to sell the Accused Products in the United States which directly infringes the '044 and '080 Patents.

43. The Supreme Court in *Global-Tech Appliances Inc. v. SEB S.A.*, 563 U.S. 754 (2011) held that induced infringement under 271(b) requires knowledge that the induced acts constitute patent infringement, but also held that the required knowledge could be shown under the doctrine of "willful blindness". The Supreme Court found two basic requirements to show "willful blindness", (1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact. The

Supreme Court specifically said: “[U]nder this formulation a willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and can almost be said to have actually known the critical facts.” As set forth above, Dr. Tan knew that Kaneka had patents covering its Ubiquinol product and knew that the DuoQuinol he created was a form of Ubiquinol. Therefore, ARN/Dr. Tan knew that there was a high probability that DFH would directly infringe Kaneka’s Ubiquinol patents by including DuoQuinol in the CoQnol product.

44. With this knowledge of high probability of infringement by DFH of Kaneka’s Ubiquinol patents, ARN deliberately proceeded to aide and encourage DFH to produce the Ubiquinol Accused Products in the United States. Without discovery, it is unknown if ARN or Dr. Tan made any effort to specifically determine if Kaneka’s patents were infringed by the Accused Products. However, if no effort was made, it can only be because ARN and Dr. Tan choose to be willfully blind by deliberately taking actions to avoid confirming the high probability that DFH would be directly infringing one or more of Kaneka’s patents by making, using, selling and including DuoQuinol Ubiquinol in the CoQnol product. Kaneka therefore alleges that ARN has been, and currently is, inducing the direct infringement of the ‘044 and ‘080 patents by DFH.

45. As a consequence of ARN inducing infringement of the ‘044 and ‘080 Patents, Kaneka has suffered, is suffering, and will continue to suffer, damages in an amount not yet determined, but no less than a reasonable royalty

PRAYER FOR RELIEF

WHEREFORE, Kaneka requests the following relief:

- a) A judgment that DFH has directly infringed the ‘044 and ‘080 Patents;

- b) A judgment that ARN has induced direct infringement of the '044 and '080 Patents;
- c) Damages from defendants adequate to compensate for Defendants infringement but, in no event, less than a reasonable royalty for past and future infringing sales;
- d) An award of Kaneka's costs and expenses in this action,
- e) Entry of a preliminary and permanent injunction, pursuant to 35 U.S.C. § 283, enjoining each of the Defendants, and all of their respective agents, servants, officers, directors, employees, and all other persons acting in concert with them, directly or indirectly, from any further acts of infringement.
- f) Such further and other relief as this Court may deem just and proper.

DEMAND FOR A JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Kaneka demands a trial by jury on all issues triable as of right by a jury.

Date: April 28, 2021

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