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AKESO HEALTH SCIENCES, LLC

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

AKESO HEALTH SCIENCES, LLC,
Plaintiff,
vs.
DESIGNS FOR HEALTH, INC.,
Defendant.

Case No. 2:16-cv-07749-SJO-PJW

**FIRST AMENDED COMPLAINT
FOR PATENT INFRINGEMENT**

DEMAND FOR JURY TRIAL

Plaintiff Akeso Health Sciences, LLC alleges as follows for its First Amended Complaint for Patent Infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*, against Defendant Designs for Health, Inc.:

THE PARTIES

1. Plaintiff Akeso Health Sciences, LLC (“Akeso”) is a limited liability company organized and existing under the laws of the State of California, with a principal place of business located at 4607 Lakeview Canyon #561, Westlake Village, California.

2. Defendant Designs for Health, Inc. (“DFH”) is a corporation organized and existing under the laws of the State of Florida with a principal place of business located at 6 Commerce Blvd. Palm Coast, FL 32164.

JURISDICTION AND VENUE

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

4. Upon information and belief, this Court has specific personal jurisdiction over DFH because DFH has placed infringing goods into the stream of commerce with the expectation that they would be purchased in the Central District of California and/or otherwise has purposefully directed activities toward the Central District of California related to the sale of infringing goods.

5. Venue for this action is proper in the Central District of California pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

'450 PATENT

6. United States Patent Number 6,500,450 (“ ‘450 patent”) is titled “Composition for Treating Migraine Headaches” and was duly and validly issued by the United States Patent and Trademark Office on December 31, 2002. A true and correct copy of the ‘450 patent is attached and incorporated herein as Exhibit A.

7. By way of example, claim 16 of the ‘450 patent recites: A method of reducing the symptoms of migraine headache comprising administering a therapeutically effective amount of parthenolide, a magnesium salt and riboflavin, the magnesium salt being provided as a salt of an organic acid.

8. Claim 16 of the ‘450 patent is infringed directly by performance of the single step of administering the claimed combination of ingredients, e.g., when someone is given and/or takes a dose of capsules or other dosage form containing the claimed combination of ingredients.

9. The ‘450 patent names Akeso’s founder, Curt Hendrix, as the sole inventor.

10. Akeso is the owner by assignment of all right, title, and interest in the ‘450 patent, including all rights to sue and collect for past damages.

1 **AKESO’S PATENTED INVENTIONS**

2 11. The ‘450 patent relates to Mr. Hendrix’s pioneering inventions for
3 improving cerebrovascular tone and reducing the occurrence and severity of
4 migraine headaches. While many compounds have been tried as remedies for
5 migraine headaches, a major challenge in formulating an effective treatment for
6 migraine headaches is combining the correct compounds at therapeutically effective
7 dosages. The inventions claimed in Akeso’s ‘450 patent overcame this challenge
8 through novel and non-obvious proprietary combinations of feverfew plant extract
9 (parthenolide), magnesium, and riboflavin.

10 12. Before the inventions of the ‘450 patent, no known dietary supplement
11 provided in a single treatment the wide range of therapeutic benefits that are
12 provided by Akeso’s patented inventions. In addition to improved cerebrovascular
13 tone, patients receiving the preferred embodiment experienced significantly reduced
14 occurrence of migraine headaches, decreased sensitivity to light and sound, reduced
15 nausea, and increased mobility.

16 13. Akeso’s MigreLief® products sold under the ‘450 patent succeeded in
17 providing natural, drug-free relief for migraine headaches where others failed,
18 meeting a long-felt but unresolved need. They have enjoyed great commercial
19 success. And they have been widely copied in a variety of infringing products,
20 including DFH’s Migranol product and many others.

21 14. Akeso makes and sells its patented MigreLief® products under the
22 ‘450 patent. In accordance with 35 U.S.C. § 287(a), Akeso marks its MigreLief®
23 products with the number of the ‘450 patent.

24 **DFH’S INFRINGEMENT**

25 15. DFH has infringed at least claim 16 of the ‘450 patent in connection
26 with its product Migranol. Notwithstanding that the product label does not
27 expressly instruct the use of the product for migraines, the incorporation of the
28 word migraine in the product name, coupled with the recommended use of a dosage

1 containing the patented combination of ingredients, confirms that the product label
 2 instructs and encourages direct infringement of at least claim 16 of the ‘450 patent.
 3 Infringement of this representative claim is alleged solely for illustrative pleading
 4 purposes, and no representation is made or implied that DFH’s conduct relative to
 5 Migranol does not infringe additional claims of the ‘450 patent. Akeso reserves the
 6 right to assert infringement of additional claims of the ‘450 patent as this action
 7 proceeds.

8 16. “Direct infringement under § 271(a) occurs where all steps of a
 9 claimed method are performed by or attributable to a single entity.” *Akamai Techs.,*
 10 *Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc). At
 11 least exemplary claim 16 of the ‘450 patent is infringed directly by DFH where the
 12 single step of the claimed method – administering Migranol – is performed by or
 13 attributable to DFH.

14 17. DFH markets, sells, and distributes Migranol on Amazon, among other
 15 channels. Attached as Exhibit B is a true and correct copy of the DFH Amazon
 16 page for Migranol. Exhibit B indicates that the product on Amazon is sold by DFH
 17 Select. DFH’s web site confirms that DFH Select is DFH’s “eCommerce solution”
 18 through which DFH sells its products on Amazon and other online stores. *See*
 19 <http://info.designsforhealth.com/dfhselect-about>. As such, DFH is the seller of the
 20 Migranol product listed on Amazon and is responsible for the associated text in
 21 Exhibit B.

22 18. As reflected in Exhibit B, the title of the product page is “Designs for
 23 Health - Migranol with Curcumin and Magnesium for Inflammation, **Treating and**
 24 **Preventing Migraines**, 90 Vegetarian Capsules,” and the “About the Product” text
 25 indicates, inter alia, “The recommended dosage for Migranol is three vegetarian
 26 capsules per day with a meal. **Taking the recommended dosage may help with**
 27 **treating and preventing migraines**.” (Emphasis added). Exhibit B further includes
 28 customer reviews confirming that customers do, in fact, use Migranol for migraine

1 relief.

2 19. Exhibit B reflects that DFH's marketing, sales, and distribution of
3 Migranol on Amazon is explicitly directed to use of Migranol for migraine relief
4 and, in fact, causes customers to use Migranol for that purpose.

5 20. DFH also distributes Migranol via the web site Pure Formulas.
6 Attached as Exhibit C is a true and correct copy of the Migranol page on Pure
7 Formulas. The description of Migranol on Exhibit C states, "Migranol by Designs
8 for Health is formulated to help prevent migraines, as well as reduce their
9 frequency and severity." As with the DFH Amazon page in Exhibit B, the Pure
10 Formulas page in Exhibit C includes customer reviews confirming that customers
11 do, in fact, use Migranol for migraine relief. Thus DFH's marketing, sales, and
12 distribution of Migranol on Pure Formulas is explicitly directed to use of Migranol
13 for migraine relief and, in fact, causes customers to use Migranol for that purpose.

14 21. Further, DFH prides itself on providing "A True Professional Line," as
15 shown in Exhibit D, which is a true and correct copy of a page on DFH's web site.
16 See http://www.designsforhealth.com/Professional_Products.html. This page states
17 that "Designs for Health works closely with the practitioners who use our products,
18 inviting feedback and suggestions from their clinical experiences" and that
19 "Designs for Health products are marketed only through qualified health care
20 practitioners and their patients through referral. Health practitioners are required to
21 provide a copy of their state license and/or professional degree, certificate, or
22 diploma. As a true professional line of nutritional supplements, Designs for Health
23 does not allow discounting its products, and actively enforces this policy."

24 22. Akeso believes that discovery regarding the foregoing statements on
25 DFH's web site, and other discovery, is likely to confirm that DFH exerts direction
26 or control over others' performance of the single step of claim 16 of the '450 patent
27 and/or that DFH is engaged in a joint enterprise with affiliated practitioners such
28 that performance of the claimed method by practitioners is attributable to DFH.

1 Akeso further believes that discovery is likely to confirm that DFH itself performs
2 the claimed method by administering Migranol in connection with product
3 development and testing and quality assurance and/or other activities.

4 23. In addition to direct infringement, DFH is liable for inducing
5 infringement under 35 U.S.C. § 271(b).

6 24. Use of Migranol as directed by DFH online (*see* Exhibits B and C) and
7 reported in Amazon and Pure Formulas reviews by users of Migranol constitutes
8 direct infringement of at least claim 16 of the '450 patent.

9 25. DFH affirmatively directs or controls health care professionals and/or
10 end-users to directly infringe by administering the recommended daily dosage that
11 includes a therapeutically effective amount of parthenolide, a magnesium salt and
12 riboflavin, the magnesium salt being provided as a salt of an organic acid.

13 26. Akeso and its MigreLief® product are well known in the dietary
14 supplement industry. Akeso's web site and every bottle of MigreLief® are marked
15 with the numbers of the '450 patent. As a result of these efforts by Akeso to give
16 constructive notice of the '450 patent, upon information and belief, DFH has actual
17 and/or constructive knowledge of Akeso's MigreLief® product and of the '450
18 patent.

19 27. In addition, DFH received actual knowledge of the '450 patent and of
20 direct infringement occurring through administration of Migranol on the date DFH
21 was served with the summons and complaint in this action, October 19, 2016.
22 *See* Dkt. No. 13.

23 28. DFH knows or should know that administration of Migranol
24 constitutes direct infringement of the '450 patent.

25 29. In addition or in the alternative, DFH was willfully blind to the
26 infringing nature of Migranol administration.

27 30. Upon information and belief, DFH knowingly induces direct
28 infringement of the '450 patent and possesses specific intent to encourage direct

1 infringement by health care practitioners and/or end-users of Migranol.

2 Accordingly, DFH is liable for inducing infringement of the '450 patent pursuant to
3 35 U.S.C. §271(b).

4 31. DFH further is liable for contributory infringement pursuant to 35
5 U.S.C. § 271(c).

6 32. The combination of a therapeutically effective amount of parthenolide,
7 a magnesium salt provided as a salt of an organic acid, and riboflavin contained in
8 Migranol is material to practicing the inventions of the '450 patent.

9 33. Administration of Migranol as directed by DFH online (*see* Exhibits B
10 and C) and reported in Amazon and Pure Formulas reviews by purchasers of
11 Migranol constitutes direct infringement of the '450 patent.

12 34. There are no substantial non-infringing uses of the patented
13 combination of a therapeutically effective amount of parthenolide, a magnesium
14 salt provided as a salt of an organic acid, and riboflavin contained in Migranol. On
15 the contrary, the only known substantial use of this combination, and the specific
16 use directed by DFH online (*see* Exhibits B and C) and reported by purchasers, is to
17 be administered for the purpose of reducing the symptoms of migraine headache in
18 a directly infringing manner.

19 35. Any other uses of the individual ingredients of Migranol, such as use
20 of feverfew for nonspecific inflammation relief and/or use of curcuminoids and
21 rosemary for anti-oxidant properties and a balanced inflammatory response and/or
22 use of magnesium for muscle relaxation, are not substantial non-infringing uses of
23 the patented combination of a therapeutically effective amount of parthenolide, a
24 magnesium salt provided as a salt of an organic acid, and riboflavin contained in
25 Migranol.

26 36. Upon information and belief, DFH has knowledge of the '450 patent
27 and of the fact that the combination of a therapeutically effective amount of
28 parthenolide, a magnesium salt provided as a salt of an organic acid, and riboflavin

1 contained in Migranol is especially made or adapted for use in infringement of the
2 '450 patent.

3 37. Accordingly, DFH is liable for contributory infringement of the '450
4 patent pursuant to 35 U.S.C. § 271(c).

5 38. Upon information and belief, DFH has knowledge of the '450 patent
6 and knows or should know that its conduct in relation to Migranol infringes the
7 '450 patent. Accordingly, DFH's infringement is and has been willful.

8 **CLAIM FOR RELIEF**

9 **(Infringement of U.S. Patent No. 6,500,450)**

10 39. Akeso repeats and realleges the allegations of the foregoing
11 Paragraphs 1 through 38 as if fully set forth herein.

12 40. DFH has directly infringed at least claim 16 of the '450 patent under
13 35 U.S.C. § 271(a), literally and/or under the doctrine of equivalents, as alleged
14 above.

15 41. DFH has indirectly infringed at least claim 16 of the '450 patent by
16 inducement under 35 U.S.C. § 271(b) by instructing and encouraging end users
17 and/or health care practitioners to directly infringe the '450 patent, literally and/or
18 under the doctrine of equivalents, as alleged above. DFH does so with knowledge
19 of the '450 patent and specific intent to encourage end users and/or health care
20 practitioners to directly infringe, literally and/or under the doctrine of equivalents.
21 End users and health care practitioners directly infringe the '450 patent, literally
22 and/or under the doctrine of equivalents, in connection with using Migranol, as
23 confirmed by the customer reviews in Exhibits B and C.

24 42. DFH also has indirectly infringed at least claim 16 of the '450 patent
25 contributorily under 35 U.S.C. § 271(c) by offering to sell and selling Migranol,
26 knowing the same to be especially made or especially adapted for use in an
27 infringement of the '450 patent, and not a staple article or commodity of commerce
28 suitable for substantial non-infringing use, as alleged above.

1 43. DFH's infringement is and has been willful, as alleged above.

2 44. Akeso has been damaged, in an amount to be determined, as a direct
3 and proximate result of DFH's infringement of the '450 patent.

4 **PRAYER FOR RELIEF**

5 WHEREFORE, Akeso respectfully requests the Court to enter judgment in
6 favor of Akeso and against DFH as to all claims asserted herein as follows:

7 A. Granting a judgment that DFH has directly infringed the '450 patent in
8 violation of 35 U.S.C. § 271(a);

9 B. Granting a judgment that DFH has indirectly infringed the '450 patent
10 in violation of 35 U.S.C. §§ 271(b) and 271(c);

11 C. Ordering DFH to pay to Akeso actual damages in the form of lost
12 profits or, in the alternative, other damages adequate to compensate for the
13 infringement, but in no event less than a reasonable royalty for the use made
14 of the patented inventions by DFH, together with pre-judgment and post-
15 judgment interest and costs as fixed by the Court, in accordance with 35
16 U.S.C. § 284;

17 D. Granting a judgment that DFH's infringement was willful and ordering
18 DFH to pay to Akeso increased damages of three times the compensatory
19 damages, in accordance with 35 U.S.C. § 284;

20 E. Granting a judgment that this case is exceptional under 35 U.S.C. §285
21 and ordering DFH to pay to Akeso its reasonable attorney fees incurred in
22 this action; and

23 F. Granting Akeso such other and further relief as this Court may deem
24 just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38 and Central District of California L.R. 38-1, Akeso demands a trial by jury on all issues so triable.

Dated: January 20, 2017

NIXON PEABODY LLP

By: /s/ Shawn G. Hansen

Attorneys for Plaintiff
AKESO HEALTH SCIENCES, LLC