

Shawn G. Hansen (SBN 197033)
shansen@nixonpeabody.com
NIXON PEABODY LLP
300 South Grand Avenue, Suite 4100
Los Angeles, CA 90071-3151
Telephone: (213) 629-6000
Facsimile: (855) 780-9262

Attorneys for Plaintiff
AKESO HEALTH SCIENCES, LLC

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

AKESO HEALTH SCIENCES, LLC,

Plaintiff,

vs.

**NUTRACEUTICAL
CORPORATION and DOES 1-10,**

Defendants.

Case No. 2:16-cv-05303-SJO-PJW

**FIRST AMENDED COMPLAINT
FOR:**

- (1) VIOLATION OF
THE LANHAM ACT,
15 U.S.C. § 1125(a);**
- (2) VIOLATION OF
CALIFORNIA BUSINESS
AND PROFESSIONS CODE
§ 17200;**
- (3) VIOLATION OF
CALIFORNIA BUSINESS
AND PROFESSIONS CODE
§ 17500; AND**
- (4) PATENT INFRINGEMENT,
35 U.S.C. § 271**

DEMAND FOR JURY TRIAL

1 Plaintiff Akeso Health Sciences, LLC (“Akeso”) alleges as follows for its
2 First Amended Complaint against Defendant Nutraceutical Corporation
3 (“Nutraceutical”).

4 **PRELIMINARY STATEMENT**

5 This case is about natural products made for the more than 38 million people
6 in the United States who suffer from migraine headaches. In that market, Akeso
7 offers its patented MigreLief® family of dietary supplement products, and
8 Nutraceutical offers a dietary supplement called Migra-Clear Ultra, as well as an
9 allegedly homeopathic drug called NaturalCare Migraine.

10 Homeopathic drugs are the top selling curative products on the market
11 behind prescription medicine. It is estimated that Americans spend over \$3 billion
12 dollars a year on the purchase of homeopathic medicine.

13 The majority of homeopathic medicine is available over the counter (“OTC”)
14 because it is considered safe for consumers to take for self-diagnosed ailments. For
15 a product to be labeled homeopathic, it must contain ingredients listed by the
16 Homeopathic Pharmacopeia Convention of the United States (“HPCUS”), but
17 solely in the potency levels set by HPCUS, which are specified in terms of dilution
18 (e.g., 1x (1/10 dilution), 2x (1/100 dilution)). Drug products containing
19 homeopathic ingredients in combination with non-homeopathic active ingredients
20 are not homeopathic drug products.

21 Most homeopathic products are so diluted that they only contain trace or
22 barely detectable levels of the initial substances. While many modern medical
23 experts argue that homeopathic products do not work, advocates claim they work
24 under the theory that “likes cure likes,” meaning a substance that causes the
25 symptoms in healthy people would cure similar symptoms of other diseases when
26 administered in low potency doses. An example would be using onion, which is
27 known to cause runny noses and eyes, to treat a cold.

1 In light of the alternative theories giving rise to homeopathic medicine,
2 homeopathic products are regulated differently from dietary supplements.
3 Homeopathic product sellers can make broader claims of what they do, what they
4 allegedly cure, and can make “drug claims” that federal law prohibits dietary
5 supplement product sellers from making.

6 Many believe that it is this greater flexibility in advertising and marketing,
7 combined with today’s consumers’ desire for “all-natural,” holistic, minimally
8 invasive treatments, that drives the billions of dollars of annual sales of
9 homeopathic products.

10 As described in more detail below, Nutraceutical knowingly mislabeled
11 NaturalCare Migraine as a homeopathic product in order to make drug claims that
12 could not be made if the product were considered a dietary supplement product. In
13 reality, as alleged below, NaturalCare Migraine is not properly labeled as a
14 homeopathic product, because it contains non-homeopathic ingredients listed as
15 other ingredients or inactive ingredients that Nutraceutical contends are, in fact,
16 active ingredients.

17 Nonetheless, Nutraceutical knowingly marketed NaturalCare Migraine as a
18 homeopathic product so it could make drug claims to advertise and sell that
19 product. In doing so, not only has Nutraceutical breached the public’s trust and
20 endangered consumers’ health, but it also schemed to compete unfairly with Akeso
21 by taking advantage of the relaxed regulatory requirements applicable to
22 homeopathic advertising and marketing, thereby stealing Akeso’s rightful market
23 share.

24 Compounding the competitive detriment to Akeso, Nutraceutical also
25 infringed Akeso’s patent rights in connection with a different product, Migra-Clear
26 Ultra, which Nutraceutical markets as a dietary supplement product and not a
27 homeopathic product.
28

1 the Central District of California and/or otherwise has purposefully directed
2 activities toward the Central District of California related to the sale of infringing
3 goods.

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

6
7 **NUTRACEUTICAL' S KNOWLEDGE OF FEDERAL LAW**

8 7. Nutraceutical sells over 7,500 nutritional supplements across its
9 various product lines, including homeopathic products and dietary supplement
10 products.

11 8. Nutraceutical is aware of the various FTC, FDA and other regulations
12 governing its manufacture, advertising, marketing and sale of its homeopathic
13 products and dietary supplement products.

14 9. Specifically, Nutraceutical is informed that OTC homeopathic drug
15 products can be marketed with drug claims while dietary supplements cannot be
16 marketed with drug claims.

17 10. Nutraceutical knows that the U.S. Food & Drug Administration
18 provides Compliance Policy Guidelines ("CPG") regarding the marketing of
19 homeopathic drugs. See CPG 7132.15, Section 400.400: "Conditions Under Which
20 Homeopathic Drugs May be Marketed."

21 (<http://www.fda.gov/iceci/compliancemanuals/compliancepolicy>
22 [guidancemanual/ucm074360.htm](http://www.fda.gov/iceci/compliancemanuals/compliancepolicy/guidancemanual/ucm074360.htm)).

23 11. Nutraceutical knows that under the CPG, a homeopathic drug is
24 exempt from regulation if:

- 25 • The active ingredient is the subject of a HPUS monograph;
- 26 • The product does not include non-homeopathic active ingredients;
- 27 • The product is homeopathically prepared;
- 28 • The claims (indications) are consistent with homeopathic usage for the

active ingredient(s) in the product; and

- The product is intended solely for self-limiting diseases amenable to self-diagnosis and treatment by consumers.

See CPG 7132.15; 2015 Nutraceutical annual report.

**NUTRACEUTICAL' S ALLEGEDLY HOMEOPATHIC MIGRAINE
PRODUCT AT ISSUE**

12. Nutraceutical manufactures, distributes, markets and sells NaturalCare Migraine.

13. NaturalCare Migraine is packaged, labeled, marketed and sold as a homeopathic remedy:



14. The label for NaturalCare Migraine lists the “active ingredients” as Belladonna 6X, Bryonia albo 6X, Epiphegus 6X, and other traditional homeopathic ingredients, all using the required dilution measurement as follows:

Indications: For the symptomatic relief of migraine headache pain.

Directions: Adults and children 12 years of age and older, take 2 capsules at the earliest sign of migraine symptoms, and if needed every 4-6 hours while symptoms persist. For severe conditions, 2 capsules may be taken every 2-4 hours while symptoms persist. Do not exceed 16 capsules per day. If your symptoms continue or worsen, please contact your doctor. For children under 12, consult your health care provider before use.

WARNINGS: If pain persists, gets worse or if new symptoms occur, consult a doctor to rule out a more serious condition. If you are pregnant or nursing, seek the advice of a health care professional before use. Not intended for use by phenylketonurics or persons with high blood pressure. Do not take with MAO inhibitors. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Active Ingredients: Belladonna 6X, 12X; Bryonia alba 6X; Cimicifuga racemosa 6X; Coffea cruda 12X; Epiphegus 6X; Gelsemium 6X; Iris versicolor 6X; Melilotus 6X; Natrum Muriaticum 6X; Onosmodium 30X; Pulsatilla 9X, 30X; Sanguinaria canadensis 6X; and Scutellaria lateriflora 6X.

Other Ingredients: Butterbur, Capsule (Gelatin, Glycerin, and Titanium Dioxide), Feverfew, Green Tea, 5-Hydroxytryptophan, Magnesium amino acid chelate, Magnesium Stearate, Pyridoxine HCl (Vit. B-6), Riboflavin (Vit. B-2), and Silica.

15. As shown above, the label for NaturalCare Migraine lists “other ingredients” including, *inter alia*, Feverfew, Magnesium Stearate, and Riboflavin.

16. As shown in Paragraph 13, above, Nutraceutical makes the following efficacy claims on the package of NaturalCare Migraine:

“For Symptomatic Relief of Migraine Headache Pain:

- Shooting Pain
- Throbbing
- Pressure”

NUTRACEUTICAL’S DIETARY SUPPLEMENT PRODUCT AT ISSUE

17. Nutraceutical’s dietary supplement product Migra-Clear Ultra is labeled and marketed as a method of reducing the symptoms of migraine headache by administering a serving of two capsules. The product label is as follows:



18. As shown above, the product label states, “Migra-Clear Ultra is a unique vitamin and herbal formula designed to help reduce the frequency and intensity of head vascular pain and discomfort.” In addition, marketing descriptions of the product state, “Migra-Clear Ultra is a unique vitamin and herbal formula

1 designed to help reduce the frequency and intensity of head vascular disturbances.
 2 ... Doctors, consulting with BioGenesis Nutraceuticals, Inc., designed MigraClear
 3 Ultra to contain the most documented and effective nutraceuticals presently known
 4 to help support the reduction of the frequency and intensity of migraine/vascular
 5 headaches.” *See, e.g.*: [http://www.nutrabiogenesis.com/catagorypages/catagory-](http://www.nutrabiogenesis.com/catagorypages/catagory-inflammation-and-pain.html)
 6 [inflammation-and-pain.html](http://www.nutrabiogenesis.com/catagorypages/catagory-inflammation-and-pain.html) and
 7 [http://www.amazon.com/BioGenesis-Nutraceuticals-Migra-Clear-Vegetarian-](http://www.amazon.com/BioGenesis-Nutraceuticals-Migra-Clear-Vegetarian-Capsules/dp/B003EE7HBY/)
 8 [Capsules/dp/B003EE7HBY/](http://www.amazon.com/BioGenesis-Nutraceuticals-Migra-Clear-Vegetarian-Capsules/dp/B003EE7HBY/). A true and correct copy of exemplary Migra-Clear
 9 Ultra marketing material is attached and incorporated herein as **Exhibit A**.

10 19. Unlike its claims with NaturalCare Migraine, upon information and
 11 belief, Nutraceutical does not make drug claims on the label of Migra-Clear Ultra
 12 or its related marketing material.

13 **AKESO’S PATENTED MIGRELIEF® PRODUCTS**

14 20. Akeso markets and sells a family of products under the name
 15 MigreLief®, including Migrelief, Migrelief Now, Kids Migrelief and Migrelief M.

16 21. Akeso makes and sells its patented MigreLief® products under United
 17 States Patent Number 6,500,450 (“ ‘450 patent”). In accordance with 35 U.S.C. §
 18 287(a), Akeso marks its MigreLief® products with the number of the ‘450 patent.
 19

20 **AKESO’S ‘450 PATENT**

21 22. The ‘450 patent is titled “Composition for Treating Migraine
 22 Headaches” and was duly and validly issued by the United States Patent and
 23 Trademark Office on December 31, 2002. A true and correct copy of the ‘450
 24 patent is attached and incorporated herein as **Exhibit B**.
 25

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

28 24. Akeso is the owner by assignment of all right, title, and interest in the

1 '450 patent, including all rights to sue and collect for past damages.

2
3 **AKESO'S PATENTED INVENTIONS**

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

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

18 27. Akeso's MigreLief® products sold under the '450 patent succeeded in
19 providing natural, drug-free relief for migraine headaches where others failed,
20 meeting a long-felt but unresolved need. They have enjoyed great commercial
21 success. And they have been widely copied in a variety of infringing products,
22 including Nutraceutical's Migra-Clear Ultra.

23
24 **NUTRACEUTICAL'S UNLAWFUL MARKETING**

25 28. Upon information and belief, Nutraceutical contends that its allegedly
26 homeopathic drug product NaturalCare Migraine allegedly anticipates and/or
27 renders obvious the '450 patent because NaturalCare Migraine allegedly contains
28 the combination of ingredients claimed in the '450 patent and allegedly was on sale

1 or in public use more than one year before the earliest effective filing date of the
2 '450 patent.

3 29. Implicit in this contention is that ingredients listed as "other
4 ingredients" on the label of NaturalCare Migraine were, in fact, "active ingredients"
5 present in amounts sufficient to meet the limitations of the claims of the '450
6 patent.

7 30. If NaturalCare Migraine were legally labeled as a homeopathic
8 product, Nutraceutical would be legally able to make drug claims for NaturalCare
9 Migraine that Akeso cannot make when marketing and advertising its patented
10 MigreLief® products.

11 31. However, FDA's CPG expressly states that, "**Drug products**
12 **containing homeopathic ingredients in combination with non-homeopathic active**
13 **ingredients are not homeopathic drug products.**" CPG 7132.15, Sec. 400.400,
14 Definitions, (2) (emphasis added).

15 32. Upon information and belief, Akeso's patented combination of
16 feverfew, magnesium, and riboflavin includes non-homeopathic ingredients. Thus,
17 if Akeso's patented combination of feverfew, magnesium, and riboflavin is truly
18 among the "active ingredients" in Nutraceutical's NaturalCare Migraine product, as
19 Nutraceutical contends, then NaturalCare Migraine is falsely labeled to have these
20 ingredients as inactive "other ingredients," is not legally a homeopathic drug, and
21 was illegally labeled, marketed, and/or sold as a homeopathic drug by
22 Nutraceutical.

23 33. Because it is subject to a different legal regime for dietary
24 supplements, Akeso cannot make such efficacy claims for its patented MigreLief®
25 products. Nutraceutical enjoys an unfair advantage in the marketplace over Akeso's
26 patented MigreLief® product by using such efficacy claims with NaturalCare
27 Migraine.

28 34. Moreover, not only do Nutraceutical's marketing practices deceive

1 customers who desire a homeopathic remedy, its practices devalue the goodwill and
 2 brand value to Akeso of the patented combination of ingredients.

4 **NUTRACEUTICAL'S UNLAWFUL SCHEME**

5 35. On information and belief, NaturalCare Migraine is not the only
 6 Nutraceutical homeopathic product that has misleading and false statements on its
 7 labeling and packaging.

8 36. On information and belief, Nutraceutical has a pattern and practice of
 9 including known ingredients and/or combination of ingredients in its homeopathic
 10 products, but lists them as inactive ingredients so that its allegedly homeopathic
 11 products can be marketed using drug claims, can be sold OTC, and will be subject
 12 to less regulation by both the FDA and FTC. Beyond NaturalCare Migraine, other
 13 such products include at least the following:

- 14 • Anxiety Relief
- 15 • Mucus Fix
- 16 • Nerve Fix
- 17 • Prosta Health
- 18 • Reflux Away
- 19 • Serra Pain
- 20 • Sleep Fix
- 21 • Vein Gard

22 37. On information and belief, Nutraceutical also includes active
 23 ingredients as inactive ingredients in the above-identified allegedly homeopathic
 24 products so that purchasers of its products get a noticeable result from taking its
 25 allegedly homeopathic products, which drives repeat business and gives
 26 Nutraceutical a competitive advantage over others in the dietary supplement
 27 business, including Akeso.

28 38. On information and belief, Nutraceutical and Does 1-10 engage in this

1 behavior for their own financial gain as they know that the market size and amount
2 of sales for homeopathic products greatly exceeds that of dietary supplements.

4 **NUTRACEUTICAL'S WILLFUL PATENT INFRINGEMENT**

5 39. In addition, Nutraceutical has willfully infringed the '450 patent in
6 connection with the dietary supplement product Migra-Clear Ultra.

7 40. Nutraceutical's conduct in connection with making, using, selling,
8 offering to sell and/or importing Migra-Clear Ultra directly infringes at least claim
9 16 of the '450 patent pursuant to 35 U.S.C. § 271(a). Infringement of this
10 representative claim is alleged solely for illustrative pleading purposes, and no
11 representation is made or implied that Nutraceutical's conduct relative to Migra-
12 Clear Ultra does not infringe additional claims of the '450 patent. Akeso reserves
13 the right to assert infringement of additional claims of the '450 patent as this action
14 proceeds.

15 41. Prior to the filing of this Action, Akeso provided to Nutraceutical a
16 preliminary, non-binding claim chart demonstrating how Nutraceutical's conduct in
17 relation to Migra-Clear Ultra meets each limitation of claim 16 of the '450 patent.

18 42. In addition to direct infringement, Nutraceutical is liable for
19 inducement of infringement under 35 U.S.C. § 271(b).

20 43. Use of Migra-Clear Ultra as directed on the product label constitutes
21 direct infringement of at least claim 16 of the '450 patent. Nutraceutical
22 affirmatively directs users to directly infringe by administering the recommended
23 daily dosage of a therapeutically effective amount of parthenolide, a magnesium
24 salt and riboflavin, the magnesium salt being provided as a salt of an organic acid.

25 44. Akeso and its MigreLief® product are well known in the dietary
26 supplement industry. Akeso's web site and every bottle of MigreLief® are marked
27 with the numbers of the '450 patent.

28 45. Nutraceutical has knowledge of the '450 patent.

1 46. Upon information and belief, Nutraceutical knowingly induces
2 infringement of the '450 patent and possesses specific intent to encourage direct
3 infringement by users of Migra-Clear Ultra. Accordingly, Nutraceutical is liable for
4 inducing infringement of the '450 patent pursuant to 35 U.S.C. §271(b).

5 47. Nutraceutical further is liable for contributory infringement pursuant
6 to 35 U.S.C. § 271(c).

7 48. The patented combination of a therapeutically effective amount of
8 parthenolide, a magnesium salt and riboflavin, the magnesium salt being provided
9 as a salt of an organic acid, contained in Migra-Clear Ultra is material to practicing
10 the inventions of the '450 patent.

11 49. Administration of Migra-Clear Ultra as directed on the label
12 constitutes direct infringement of the '450 patent.

13 50. There are no substantial non-infringing uses of the patented
14 combination of a therapeutically effective amount of parthenolide, a magnesium
15 salt and riboflavin, the magnesium salt being provided as a salt of an organic acid,
16 contained in Migra-Clear Ultra. On the contrary, the only known use, and the
17 specific use directed on the product label, is to be administered for the purpose of
18 reducing the symptoms of migraine headache in a directly infringing manner.

19 51. Nutraceutical has knowledge of the '450 patent and of the fact that the
20 patented combination of a therapeutically effective amount of parthenolide, a
21 magnesium salt and riboflavin, the magnesium salt being provided as a salt of an
22 organic acid, contained in Migra-Clear Ultra is especially made or adapted for use
23 in infringement of the '450 patent.

24 52. Accordingly, Nutraceutical is liable for contributory infringement of
25 the '450 patent pursuant to 35 U.S.C. § 271(c).

26 53. Nutraceutical has knowledge of the '450 patent but has failed to
27 provide any reason why its conduct in relation to Migra-Clear Ultra does not
28 infringe the '450 patent. Accordingly, Nutraceutical's infringement is and has been

1 willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant,
2 and/or characteristic of a pirate.

3
4 **FIRST CLAIM FOR RELIEF**

5 **(Violation of the Lanham Act, 15 U.S.C. § 1125(a))**

6 54. Akeso repeats and realleges the allegations of the foregoing
7 Paragraphs 1 through 53 as if fully set forth herein.

8 55. NaturalCare Migraine is not a homeopathic drug within the meaning of
9 applicable federal law.

10 56. Nutraceutical's marketing, labeling and advertising of NaturalCare
11 Migraine as a homeopathic drug is false, misleading and deceptive.

12 57. Nutraceutical's statements of efficacy regarding NaturalCare Migraine
13 are unlawful and cannot be made for OTC drugs and/or dietary supplements that are
14 not homeopathic.

15 58. Nutraceutical's marketing, labeling and advertising of NaturalCare
16 Migraine as a homeopathic drug that provides symptomatic relief of migraine
17 headache pain is fraudulent because, on information and belief, Nutraceutical
18 knows or should know that the product does not legally qualify as a homeopathic
19 product and/or that the benefits of the product derive from ingredients falsely listed
20 as other ingredients or inactive ingredients, and Nutraceutical intentionally induces
21 consumers to purchase NaturalCare Migraine in reliance on the product being
22 homeopathic and having active ingredients as shown on the label.

23 59. Nutraceutical's marketing, labeling and advertising of NaturalCare
24 Migraine as an allegedly homeopathic drug that provides symptomatic relief of
25 migraine headache pain provides an unfair advantage against Akeso's marketing
26 and sale of MigreLief® in the marketplace because Akeso does not make such
27 efficacy statements in compliance with laws governing dietary supplements.

28 60. Nutraceutical has caused its advertising of NaturalCare Migraine as an

1 allegedly homeopathic drug that provides symptomatic relief of migraine headache
2 pain to enter interstate commerce, by virtue of online advertising, sales and
3 shipping amongst the states.

4 61. On information and belief, Akeso has suffered lost sales, reduced
5 revenue and reduced market share and good will as a result of Nutraceutical's false,
6 fraudulent, deceptive and misleading advertising of NaturalCare Migraine as
7 allegedly homeopathic and effective for symptomatic relief of migraine headache
8 pain.

9 62. Nutraceutical's false advertising of NaturalCare Migraine as an
10 allegedly homeopathic drug is likely to deceive, and to have deceived, the public.

11 63. Nutraceutical's apparent business practice of listing active ingredients
12 as other ingredients so it may falsely identify the drug as homeopathic, as it has
13 done for NaturalCare Migraine and the other products listed in Paragraph 36,
14 above, is a willful and deliberate attempt to skirt the marketing and labeling
15 regulations of the FDA and FTC and to create an unfair business advantage against
16 Akeso and other manufacturers, suppliers and providers of dietary supplement
17 products.

18 64. Pursuant to 15 U.S.C. § 1116, Akeso is entitled to injunctive relief to
19 prohibit Nutraceutical from any further advertising, marketing or sales of
20 NaturalCare Migraine as a homeopathic drug that provides relief for migraine
21 headaches.

22 65. Pursuant to 15 U.S.C. § 1117, and as a result of Nutraceutical's
23 violation of 15 U.S.C. § 1125(a), Akeso is entitled to recovery of (1)
24 Nutraceutical's profits from sales of NaturalCare Migraine, (2) damages sustained
25 by Akeso in an amount to be determined at trial, (3) the costs of this action, and (4)
26 Akeso's reasonable attorney fees incurred herein.

SECOND CLAIM FOR RELIEF

(Violation of California Business and Professions Code § 17200)

66. Akeso repeats and realleges the allegations of the foregoing Paragraphs 1 through 65 as if fully set forth herein.

67. NaturalCare Migraine is not a homeopathic drug within the meaning of applicable federal law.

68. Nutraceutical's marketing, labeling and advertising of NaturalCare Migraine as a homeopathic drug is false, misleading and deceptive.

69. Nutraceutical's statements of efficacy regarding NaturalCare Migraine are unlawful and cannot be made for OTC drugs and/or dietary supplements that are not homeopathic.

70. Nutraceutical's marketing, labeling and advertising of NaturalCare Migraine as a homeopathic drug that provides symptomatic relief of migraine headache pain is fraudulent because, on information and belief, Nutraceutical knows or should know that the product does not legally qualify as a homeopathic product and/or that the benefits of the product derive from ingredients falsely listed as other ingredients or inactive ingredients and Nutraceutical intentionally induces consumers to purchase NaturalCare Migraine in reliance on the product being homeopathic and having active ingredients as shown on the label.

71. Nutraceutical's marketing, labeling and advertising of NaturalCare Migraine as a homeopathic drug that provides symptomatic relief of migraine headache pain provides an unfair advantage against Akeso's marketing and sale of MigreLief® in the marketplace because Akeso does not make such efficacy statements in compliance with laws governing dietary supplements.

72. On information and belief, Akeso has suffered lost sales, reduced revenue and reduced market share and good will as a result of Nutraceutical's false, fraudulent, deceptive and misleading advertising of NaturalCare Migraine as homeopathic and symptomatic relief of migraine headache pain.

1 MigreLief® in the marketplace because Akeso does not make such efficacy
2 statements in compliance with laws governing dietary supplements.

3 81. On information and belief, Akeso has suffered lost sales, reduced
4 revenue and reduced market share as a result of Nutraceutical's false, fraudulent,
5 deceptive and misleading advertising of NaturalCare Migraine as homeopathic and
6 symptomatic relief of migraine headache pain.

7 82. Nutraceutical's false advertising of NaturalCare Migraine as a
8 homeopathic drug is likely to deceive, and to have deceived, the public.

9 83. Akeso is entitled to injunctive relief to prohibit Nutraceutical from any
10 further advertising, marketing or sales of NaturalCare Migraine as a homeopathic
11 drug that provides relief for migraine headaches.

12 13 **FOURTH CLAIM FOR RELIEF**

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

15 84. Akeso repeats and realleges the allegations of the foregoing
16 Paragraphs 1 through 83 as if fully set forth herein.

17 85. Nutraceutical has directly infringed at least claim 16 of the '450 patent
18 under 35 U.S.C. § 271(a), literally and/or under the doctrine of equivalents, by
19 using Migra-Clear Ultra.

20 86. Nutraceutical has indirectly infringed at least claim 16 of the '450
21 patent by inducement under 35 U.S.C. § 271(b) by instructing and encouraging end
22 users and/or health care practitioners to directly infringe the '450 patent, literally
23 and/or under the doctrine of equivalents. Nutraceutical did so with knowledge of
24 the '450 patent and specific intent to encourage end users and/or health care
25 practitioners to directly infringe, literally and/or under the doctrine of equivalents.
26 End users and health care practitioners directly infringed the '450 patent, literally
27 and/or under the doctrine of equivalents, in connection with using Migra-Clear
28 Ultra.

- 1 B. Issuing an injunction that prohibits Nutraceutical from marketing,
- 2 advertising or selling NaturalCare Migraine as a homoepathic drug;
- 3 C. Ordering Nutraceutical to pay Akeso's attorney fees, incurred here,
- 4 pursuant to California Code of Civil Procedure § 1021.5; and
- 5 D. Granting Akeso such other and further relief as this Court may deem
- 6 just and proper.

7 **Third Claim for Relief:**

- 8 A. Granting a judgment that Nutraceutical violated California Business
- 9 and Professions Code §17500; and
- 10 B. Issuing an injunction that prohibits Nutraceutical from marketing,
- 11 advertising or selling NaturalCare Migraine as a homoepathic drug;
- 12 C. Ordering Nutraceutical to pay Akeso's attorney fees, incurred here,
- 13 pursuant to California Code of Civil Procedure § 1021.5; and
- 14 D. Granting Akeso such other and further relief as this Court may deem
- 15 just and proper.

16 **Fourth Claim for Relief:**

- 17 A. Granting a judgment that Nutraceutical has directly infringed the '450
- 18 patent in violation of 35 U.S.C. § 271(a);
- 19 B. Granting a judgment that Nutraceutical has indirectly infringed the
- 20 '450 patent in violation of 35 U.S.C. §§ 271(b) and 271(c);
- 21 C. Ordering Nutraceutical to pay to Akeso actual damages in the form of
- 22 lost profits or, in the alternative, other damages adequate to
- 23 compensate for the infringement, but in no event less than a reasonable
- 24 royalty for the use made of the patented inventions by Nutraceutical,
- 25 together with pre-judgment and post-judgment interest and costs as
- 26 fixed by the Court, in accordance with 35 U.S.C. § 284;
- 27 D. Granting a judgment that Nutraceutical's infringement was willful and
- 28 ordering Nutraceutical to pay to Akeso increased damages of three

1 times the compensatory damages, in accordance with 35 U.S.C. § 284;
2 E. Granting a judgment that this case is exceptional under 35 U.S.C. §285
3 and ordering Nutraceutical to pay to Akeso its reasonable attorney fees
4 incurred in this action; and
5 F. Granting Akeso such other and further relief as this Court may deem
6 just and proper.
7

8 **JURY DEMAND**

9 Pursuant to Federal Rule of Civil Procedure 38 and Central District of
10 California L.R. 38-1, Akeso demands a trial by jury on all issues so triable.
11

12 Dated: February 13, 2017

NIXON PEABODY LLP

13 By: /s/ Shawn Hansen

14 *Attorneys for Plaintiff*
15 AKESO HEALTH SCIENCES, LLC
16
17

18 4822-5428-9473.3
19
20
21
22
23
24
25
26
27
28