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

UNIVERSITY OF SOUTH FLORIDA	)
BOARD OF TRUSTEES, UNIVERSITY OF	)
SOUTH FLORIDA RESEARCH	)
FOUNDATION, INC., and AXCESS	)
GLOBAL SCIENCES, LLC,	)
	) C.A. No
Plaintiffs,	)
	) JURY TRIAL DEMANDED
v.	)
PERFECT KETO, LLC and	)
PERFECT KETO HOLDINGS, LLC,	)
	)
Defendants.	)

## **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff University of South Florida Board of Trustees, University of South Florida Research Foundation, Inc., and Axcess Global Sciences, LLC ("Plaintiffs"), for their complaint against Defendants Perfect Keto, LLC and Perfect Keto Holdings, LLC (collectively, "Perfect Keto" or "Defendants") allege as follows:

#### **THE PARTIES**

- 1. The University of South Florida Board of Trustees ("USF-BOT") is the governing body for the University of South Florida, a public university of the State of Florida, and the University of South Florida Research Foundation, Inc. ("USF-RF") (collectively, "USF") is a direct support organization for the University of South Florida, each having a principal place of business at 4202 E. Fowler Avenue, Tampa, FL 33620, USA.
- 2. Plaintiff Axcess Global Sciences, LLC ("AGS") is a Utah limited liability company with a principal place of business at 2157 Lincoln Street, Salt Lake City, UT 84106.

- 3. Defendant Perfect Keto, LLC ("PK") is a Delaware Limited Liability Corporation with its principal place of business at 1800 East 4th Street, Unit 101, Austin, TX 78702.
- 4. Defendant Perfect Keto Holdings, LLC ("PKH") is a Delaware Limited Liability Corporation with its principal place of business at 1800 East 4th Street, Unit 101, Austin, TX 78702.
- 5. Joinder of PK and PKH in this action and consolidation for trial is appropriate under 35 U.S.C. § 299. Plaintiffs asserts claims for relief jointly, severally, or in the alternative against PKH and its wholly owned subsidiary PK arising from the making, using, importing into the United States, offering for sale, and/or selling of the same infringing products. Common questions of fact will arise in this action relating to Defendants' infringement and liability.

## **JURISDICTION AND VENUE**

- 6. This Court has subject-matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*.
- 7. This Court has personal jurisdiction over Defendants because Defendants are entities each organized and existing under the laws of the State of Delaware.
- 8. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Defendants are entities each organized and existing under the laws of the State of Delaware, and therefore each resides in the District of Delaware.

## **BACKGROUND**

9. Plaintiffs USF-BOT and USF-RF, through tenured professors and researchers like Dr. Dominic ("Dom") D'Agostino, are innovators in the fields of metabolic health, ketosis, and ketogenic diets. Dr. D'Agostino's research relates primarily to the benefits of nutritional and therapeutic ketosis and the development of oral ketone supplements that may safely elevate blood

ketone levels. Dr. D'Agostino's inventions at issue in this litigation are described in U.S. Patent Nos. 9,138,420; 9,675,577; and 10,646,462 (collectively, the "Asserted USF Patents") as compositions of ketone precursors comprising "at least one medium chain fatty acid, or an ester thereof such as a medium chain triglyceride, and a  $\beta$ -hydroxybutyrate ketone source or precursor." *See* U.S. Patent No. 10,646,462 (the "'462 Patent") at 6:37-39.

- 10. Plaintiff AGS exclusively licenses the Asserted USF Patents. In addition, Plaintiff AGS is the owner of several United States patents including U.S. Patent Nos. 10,292,952; 11,020,362; and 11,241,403 (collectively, the "Asserted AGS Patents") in the field of exogenous ketones and ketogenic precursor supplement products. The inventions of the Asserted AGS Patents relate to compositions that aid the body in producing and sustaining elevated levels of ketone bodies in the blood and assisting in the body's transition into nutritional ketosis.
- 11. As one example, the Asserted AGS Patents describe compositions for increasing blood ketone levels using various combinations of beta-hydroxybutyrate salts, which are useful in inducing and sustaining a state of nutritional ketosis. Ketosis is described as:

"Ketosis" as used herein refers to a subject having blood ketone levels within the range of about 0.5 mmol/L and about 16 mmol/L in a subject. Ketosis may improve mitochondrial function, decrease reactive oxygen species production, reduce inflammation and increase the activity of neurotrophic factors.

U.S. Patent No. 11,020,362 (the "'362 Patent") at 6:13-21.

12. Defendants sell supplement products on their website and on Amazon.com that practice the inventions of the Asserted USF Patents and the Asserted AGS Patents, including the supplement products depicted below:



**Exogenous Ketones Drink Mix** 

https://shop.perfectketo.com/products/keto-drink-mix



**Keto BHB Capsules** 

https://shop.perfectketo.com/products/keto-bhb-capsules



**Perform: Keto Pre-Workout Drink** 

https://shop.perfectketo.com/products/keto-pre-workout-drink



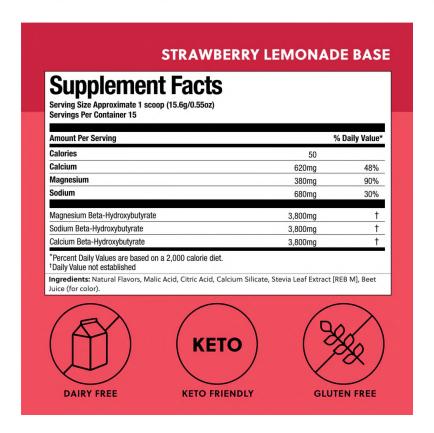
# **Keto Nootropic**

https://shop.perfectketo.com/products/keto-nootropics

13. The Defendants describe the benefits of their Exogenous Ketones Drink Mix supplement product as "support[ing] ketosis," and as "[o]ur most delicious tasting BHB exogenous

ketone Base yet." The Defendants further state that its Exogenous Ketones Drink Mix will "[b]oost ketone levels" and "support a keto diet," *see* https://get.perfectketo.com/products/, together with the benefits and supplement facts below:

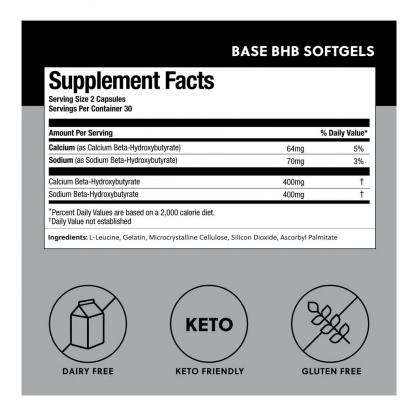
- ✓ Made to: Help reach ketosis, maintain energy levels, curb appetite, hydrate, and minimize keto flu symptoms.
- Sweetened with monk fruit for balanced sweetness
- Added electrolytes for optimal hydration
- Completely clean -- no artificial sweeteners or junk
- Free U.S. shipping for orders over \$60, and a risk-free quality guarantee



**Exogenous Ketones Drink Mix** 

https://shop.perfectketo.com/products/keto-drink-mix

- 14. The Defendants describe their Keto BHB Capsules as "[t]he easiest way to shuttle ketones into your body. Contains electrolytes to boost mental clarity and energy levels," together with the benefits and supplement facts below:
  - ✓ Made to: Help reach ketosis, maintain energy levels, curb appetite, hydrate, and minimize keto flu symptoms.
  - Capsules allow for easy, adjustable dosing
  - No aftertaste
  - Contains electrolytes

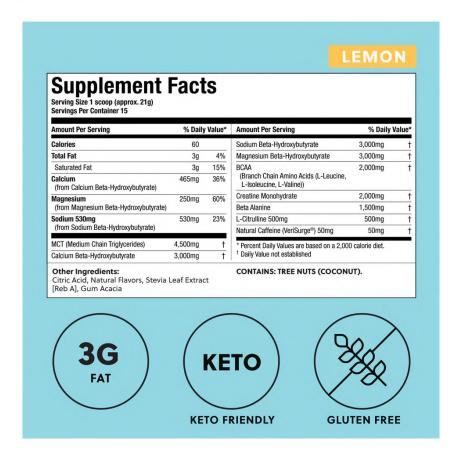


**Keto BHB Capsules** 

https://shop.perfectketo.com/products/keto-bhb-capsules

15. The Defendants describe their Perform: Keto Pre-Workout Drink as "[a] clean source of energy to supporting athletic performance on the ketogenic diet" together with the benefits and supplement facts below:

- ✓ Made to: Support strength and endurance, help you power through the day
- Less caffeine compared to traditional pre-workout formulas

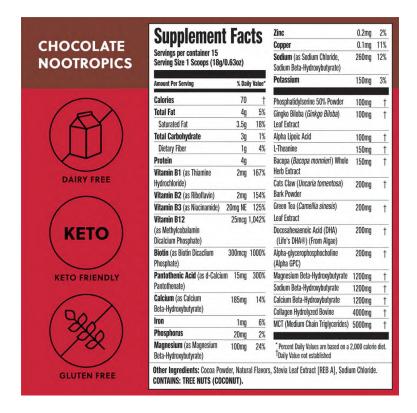


**Perform: Keto Pre-Workout Drink** 

https://shop.perfectketo.com/products/keto-pre-workout-drink

16. The Defendants describe their Keto Nootropic supplement product as "[k]etones, herbs, MCTs, and collagen to fuel and energize the mind" together with the benefits and supplement facts below:

- Made to: increase mental clarity and focus, provide energy, keep you fuller long
- Supports short term healthy brain function and helps maintain long term brain health
- 9 research-backed ingredients to support healthy cognitive function



**Keto Nootropic** 

https://shop.perfectketo.com/products/keto-nootropics

#### COUNT I – INFRINGEMENT OF U.S. PATENT NO. 9,138,420

- 17. Plaintiffs incorporate all of the allegations of the preceding paragraphs as if fully set forth herein.
- 18. On September 22, 2015, U.S. Patent No. 9,138,420 (the "'420 Patent"), titled "Compositions and Methods for Producing Elevated and Sustained Ketosis" was duly and legally issued. A true and correct copy of the '420 Patent is attached as Exhibit A.

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- 19. USF is the owner of the '420 Patent and AGS is an exclusive licensee of the '420 Patent.
- 20. Defendants make, use, offer for sale, sell, and distribute ketone supplement products that practice the invention of the '420 Patent (the "Accused Products") including the exemplary products sold by Defendants as "Perform: Keto Pre-Workout Drink" and "Keto Nootropic" exogenous ketone supplement products.
- 21. Exemplary claim 3 of the '420 Patent, which depends from claim 1, is reproduced below:
  - 1. A composition, comprising:

at least one medium chain fatty acid or ester thereof in an amount between about 5 grams and about 50 grams; and

at least one beta-hydroxybutyrate compound in an amount between about 2 grams and about 50 grams, wherein the at least one betahydroxybutyrate compound is comprised of a beta-hydroxybutyrate salt.

3. The composition of claim 1, wherein the at least one beta-hydroxybutyrate compound comprises a salt mixture comprising a plurality of sodium beta-hydroxybutyrate, potassium beta-hydroxybutyrate, calcium beta-hydroxybutyrate, or magnesium beta-hydroxybutyrate.

'420 Patent, claim 3.

- 22. One or more Accused Products infringe at least claim 3 of the '420 Patent, which depends from claim 1, in the exemplary manner shown below.
  - 1. A composition, comprising:

at least one medium chain fatty acid or ester thereof in an amount between about 5 grams and about 50 grams; and

at least one beta-hydroxybutyrate compound in an amount between about 2 grams and about 50 grams, wherein the at least one betahydroxybutyrate compound is comprised of a beta-hydroxybutyrate salt. 3. The composition of claim 1, wherein the at least one beta-hydroxybutyrate compound comprises a salt mixture comprising a plurality of sodium beta-hydroxybutyrate, potassium beta-hydroxybutyrate, calcium beta-hydroxybutyrate, or magnesium beta-hydroxybutyrate.

'420 Patent, claim 3.



**Keto Nootropic** 

https://shop.perfectketo.com/products/keto-nootropics

- 23. The Accused Products infringe at least claim 3 of the '420 Patent, which depends from claim 1, in the exemplary manner shown below.
  - 1. A composition, comprising:

at least one medium chain fatty acid or ester thereof in an amount between about 5 grams and about 50 grams; and

at least one beta-hydroxybutyrate compound in an amount between about 2 grams and about 50 grams, wherein the at least one betahydroxybutyrate compound is comprised of a betahydroxybutyrate salt.

3. The composition of claim 1, wherein the at least one beta-hydroxybutyrate compound comprises a salt mixture comprising a plurality of sodium beta-hydroxybutyrate, potassium beta-hydroxybutyrate, calcium beta-hydroxybutyrate, or magnesium beta-hydroxybutyrate.

'420 Patent, claim 3.



**Keto Nootropic** 

https://shop.perfectketo.com/products/keto-nootropics

24. Defendants have directly infringed at least claim 3 of the '420 Patent in the United States by making, using, offering for sale, selling, and/or importing the Accused Products in violation of 35 U.S.C. § 271(a). As such, Defendants are liable for infringement of the '420 Patent under 35 U.S.C. § 271(a).

- 25. Defendants are on notice of their infringement of the '420 Patent having received actual notice of its infringement from the Plaintiffs.
- 26. Defendants have willfully infringed the '420 Patent with knowledge of the '420 Patent or was willfully blind to the '420 Patent and the risk of the Defendants' infringement.
- 27. Defendants' acts of infringement have caused damage to Plaintiffs. Plaintiffs are therefore entitled to recover damages sustained as a result of Defendants' wrongful acts in an amount that is to be proven at trial.

## COUNT II – INFRINGEMENT OF U.S. PATENT NO. 9,675,577

- 28. Plaintiffs incorporate all of the allegations of the preceding paragraphs as if fully set forth herein.
- 29. On June 13, 2017, the '577 Patent, titled "Compositions and Methods for Producing Elevated and Sustained Ketosis" was duly and legally issued. A true and correct copy of the '577 Patent is attached as Exhibit B.
- 30. USF is the owner of the '577 Patent and AGS is the exclusive licensee of the '577 Patent.
- 31. Defendants make, use, offer for sale, sell, and distribute ketone supplement products that practice the invention of the '577 Patent (the "Accused Products") including the exemplary products sold by Defendants as "Perform: Keto Pre-Workout Drink" and "Keto Nootropic" exogenous ketone supplement products.
- 32. Exemplary claim 2 of the '577 Patent, which depends from claim 1, is reproduced below:
  - 1. A method of promoting or sustaining ketosis in a mammal, comprising:

administering at least one medium chain fatty acid or ester thereof in an amount between about 5 grams and about 50 grams per day for at least one day; and

administering at least one beta-hydroxybutyrate compound, where the at least one beta-hydroxybutyrate compound is beta-hydroxybutyrate monomer salt in an amount between about 2 grams and about 50 grams per day for at least one day.

2. The method of claim 1, wherein the at least one beta-hydroxybutyrate compound comprises one or more of a beta-hydroxy butyrate sodium salt, beta-hydroxy butyrate potassium salt, beta-hydroxy butyrate calcium salt, beta-hydroxy butyrate magnesium salt, sodium beta-hydroxybutyrate, arginine beta-hydroxybutyrate, beta-hydroxy butyrate sodium salt and beta-hydroxy butyrate potassium salt, lysine beta-hydroxybutyrate, histidine beta-hydroxybutyrate, ornithine beta-hydroxybutyrate, creatine beta-hydroxybutyrate, agmatine beta-hydroxybutyrate, citrulline beta-hydroxybutyrate, and combinations thereof.

'577 Patent, claim 2.

- 33. One or more Accused Products infringe at least claim 2 of the '577 Patent, which depends from claim 1, to the extent the preamble is limiting, in the exemplary manner shown below.
  - 1. A method of promoting or sustaining ketosis in a mammal, comprising:

administering at least one medium chain fatty acid or ester thereof in an amount between about 5 grams and about 50 grams per day for at least one day; and

administering at least one beta-hydroxybutyrate compound, where the at least one beta-hydroxybutyrate compound is beta-hydroxybutyrate monomer salt in an amount between about 2 grams and about 50 grams per day for at least one day.

2. The method of claim 1, wherein the at least one beta-hydroxybutyrate compound comprises one or more of a beta-hydroxy butyrate sodium salt, beta-hydroxy butyrate potassium salt, beta-hydroxy butyrate calcium salt, beta-hydroxy butyrate magnesium salt, sodium beta-hydroxybutyrate, arginine beta-hydroxybutyrate, beta-hydroxy butyrate sodium salt and beta-hydroxy butyrate potassium salt, lysine beta-hydroxybutyrate, histidine beta-hydroxybutyrate, ornithine beta-hydroxybutyrate, creatine beta-

hydroxybutyrate, agmatine beta-hydroxybutyrate, citrulline beta-hydroxybutyrate, and combinations thereof.

'577 Patent, claim 2.



https://shop.perfectketo.com/products/keto-nootropics

- 34. The Accused Products further infringe at least claim 2 of the '577 Patent, which depends from claim 1, in the exemplary manner shown below.
  - 1. A method of promoting or sustaining ketosis in a mammal, comprising:
    - administering at least one medium chain fatty acid or ester thereof in an amount between about 5 grams and about 50 grams per day for at least one day; and
    - administering at least one beta-hydroxybutyrate compound, where the at least one beta-hydroxybutyrate compound is beta-hydroxybutyrate monomer salt in an amount between about 2 grams and about 50 grams per day for at least one day.
  - 2. The method of claim 1, wherein the at least one beta-hydroxybutyrate compound comprises one or more of a beta-hydroxy butyrate sodium salt, beta-hydroxy butyrate potassium salt, beta-hydroxy butyrate calcium salt,

beta-hydroxy butyrate magnesium salt, sodium beta-hydroxybutyrate, arginine beta-hydroxybutyrate, beta-hydroxy butyrate sodium salt and beta-hydroxy butyrate potassium salt, lysine beta-hydroxybutyrate, histidine beta-hydroxybutyrate, ornithine beta-hydroxybutyrate, creatine beta-hydroxybutyrate, agmatine beta-hydroxybutyrate, citrulline beta-hydroxybutyrate, and combinations thereof.

'577 Patent, claim 2.



**Keto Nootropic** 

https://shop.perfectketo.com/products/keto-nootropics

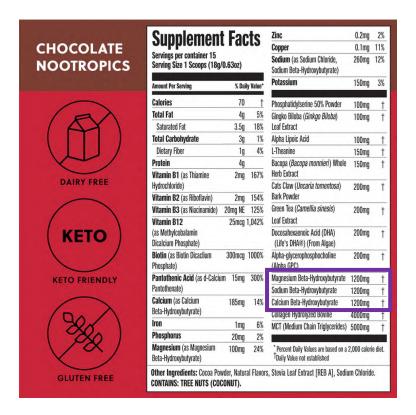
- 35. The Accused Products further infringe at least claim 2 of the '577 Patent, which depends from claim 1, in the exemplary manner shown below.
  - 1. A method of promoting or sustaining ketosis in a mammal, comprising:

administering at least one medium chain fatty acid or ester thereof in an amount between about 5 grams and about 50 grams per day for at least one day; and

administering at least one beta-hydroxybutyrate compound, where the at least one beta-hydroxybutyrate compound is betahydroxybutyrate monomer salt in an amount between about 2 grams and about 50 grams per day for at least one day.

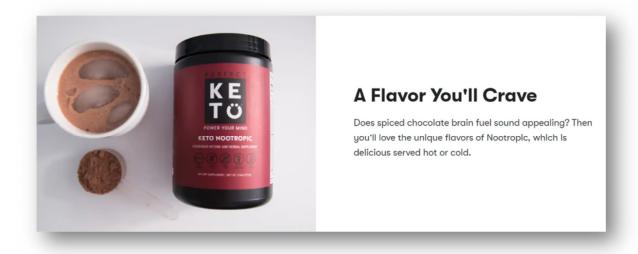
2. The method of claim 1, wherein the at least one beta-hydroxybutyrate compound comprises one or more of a beta-hydroxy butyrate sodium salt, beta-hydroxy butyrate potassium salt, beta-hydroxy butyrate calcium salt, beta-hydroxy butyrate magnesium salt, sodium betahydroxybutyrate, arginine beta-hydroxybutyrate, beta-hydroxy butyrate sodium salt and beta-hydroxy butyrate potassium salt, lysine betahydroxybutyrate, histidine beta-hydroxybutyrate, ornithine betahydroxybutyrate, creatine beta-hydroxybutyrate, agmatine betahydroxybutyrate, beta-hydroxybutyrate, and combinations citrulline thereof.

'577 Patent, claim 2.



**Keto Nootropic** 

https://shop.perfectketo.com/products/keto-nootropics



https://shop.perfectketo.com/products/keto-nootropics

- 36. Defendants have indirectly infringed at least claim 2 of the '577 Patent in the United States by actively inducing infringement through instructions provided to consumers regarding the use of the Accused Products in violation of 35 U.S.C. § 271(b). The Defendants provide their customers with the supplement facts and product instructions shown above and, as such, induces infringement of at least claim 2. As such, Defendants are liable for indirect infringement of the '577 Patent under 35 U.S.C. § 271(b).
- 37. Defendants are on notice of its infringement of the '577 Patent having received actual notice of their infringement from the Plaintiffs.
- 38. Defendants have willfully infringed the '577 Patent with knowledge of the '577 Patent or were willfully blind to the '577 Patent and the risk of the Defendants' infringement.
- 39. Defendants' acts of infringement have caused damage to Plaintiffs. Plaintiffs are therefore entitled to recover damages sustained as a result of Defendants' wrongful acts in an amount that is to be proven at trial.

# COUNT III – INFRINGEMENT OF U.S. PATENT NO. 10,646,462

- 40. Plaintiffs incorporate all of the allegations of the preceding paragraphs as if fully set forth herein.
- 41. On May 12, 2020, the '462 Patent, titled "Compositions and Methods for Producing Elevated and Sustained Ketosis" was duly and legally issued. A true and correct copy of the '462 Patent is attached as Exhibit C.
- 42. USF is the owner of the '462 Patent and AGS is the exclusive licensee of the '462 Patent.
- 43. Defendants make, use, offer for sale, sell, and distribute ketone supplement products that practice the invention of the '462 Patent (the "Accused Products") including the exemplary products sold by Defendants as "Perform: Keto Pre-Workout Drink" and "Keto Nootropic" exogenous ketone supplement products.
- 44. Exemplary claim 4 of the '462 Patent, which depends from claim 1, is reproduced below:
  - 1. A composition for inducing ketosis, suppressing appetite, or promoting weight loss in a mammal, comprising therapeutically effective amounts of:
    - at least one medium chain fatty acid or ester thereof; and
    - a beta-hydroxybutyrate monomer salt mixture comprising a plurality of beta-hydroxybutyrate monomer salts with at least two beta-hydroxybutyrate monomer salts selected from the group consisting of sodium beta-hydroxybutyrate, potassium beta-hydroxybutyrate, calcium beta-hydroxybutyrate, magnesium beta-hydroxybutyrate, lithium beta-hydroxybutyrate, arginine beta-hydroxybutyrate, lysine beta-hydroxybutyrate, histidine beta-hydroxybutyrate, ornithine beta-hydroxybutyrate, creatine beta-hydroxybutyrate, agmatine beta-hydroxybutyrate, and citrulline beta-hydroxybutyrate.
  - 4. The composition of claim 1, wherein the beta-hydroxybutyrate monomer salt mixture comprises at least three of sodium beta-hydroxybutyrate,

potassium beta-hydroxybutyrate, calcium beta-hydroxybutyrate, or magnesium beta-hydroxybutyrate.

'462 Patent, claim 4.

- 45. One or more Accused Products infringe at least claim 4 of the '462 Patent, which depends from claim 1, to the extent the preamble is limiting, in the exemplary manner shown below.
  - 1. A composition for inducing ketosis, suppressing appetite, or promoting weight loss in a mammal, comprising therapeutically effective amounts of:

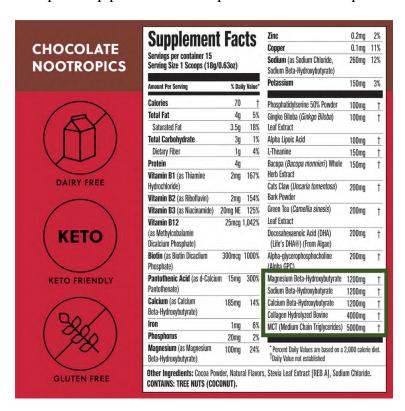
at least one medium chain fatty acid or ester thereof; and

- a beta-hydroxybutyrate monomer salt mixture comprising a plurality of beta-hydroxybutyrate monomer salts with at least two beta-hydroxybutyrate monomer salts selected from the group consisting of sodium beta-hydroxybutyrate, potassium beta-hydroxybutyrate, calcium beta-hydroxybutyrate, magnesium beta-hydroxybutyrate, lithium beta-hydroxybutyrate, arginine beta-hydroxybutyrate, lysine beta-hydroxybutyrate, histidine beta-hydroxybutyrate, ornithine beta-hydroxybutyrate, creatine beta-hydroxybutyrate, agmatine beta-hydroxybutyrate, and citrulline beta-hydroxybutyrate.
- 4. The composition of claim 1, wherein the beta-hydroxybutyrate monomer salt mixture comprises at least three of sodium beta-hydroxybutyrate, potassium beta-hydroxybutyrate, calcium beta-hydroxybutyrate, or magnesium beta-hydroxybutyrate.

<sup>&#</sup>x27;462 Patent, claim 4.



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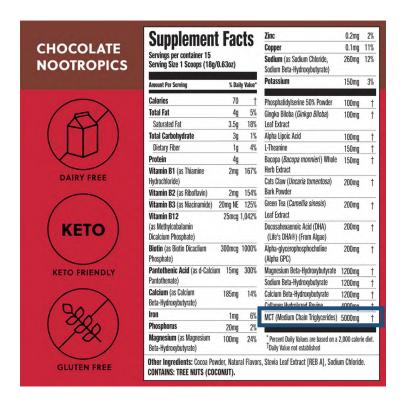
- 46. The Accused Products further infringe at least claim 4 of the '462 Patent, which depends from claim 1, in the exemplary manner shown below.
  - 1. A composition for inducing ketosis, suppressing appetite, or promoting weight loss in a mammal, comprising therapeutically effective amounts of:

## at least one medium chain fatty acid or ester thereof; and

a beta-hydroxybutyrate monomer salt mixture comprising a plurality of beta-hydroxybutyrate monomer salts with at least two beta-hydroxybutyrate monomer salts selected from the group consisting of sodium beta-hydroxybutyrate, potassium beta-hydroxybutyrate, calcium beta-hydroxybutyrate, magnesium beta-hydroxybutyrate, lithium beta-hydroxybutyrate, arginine beta-hydroxybutyrate, lysine beta-hydroxybutyrate, histidine beta-hydroxybutyrate, ornithine beta-hydroxybutyrate, creatine beta-hydroxybutyrate, agmatine beta-hydroxybutyrate, and citrulline beta-hydroxybutyrate.

4. The composition of claim 1, wherein the beta-hydroxybutyrate monomer salt mixture comprises at least three of sodium beta-hydroxybutyrate, potassium beta-hydroxybutyrate, calcium beta-hydroxybutyrate, or magnesium beta-hydroxybutyrate.

'462 Patent, claim 4.



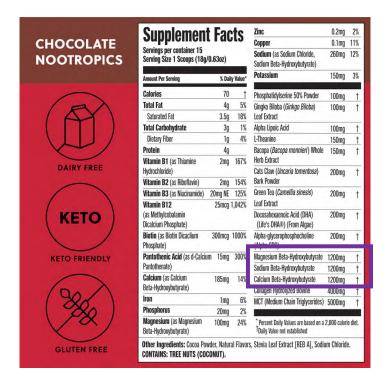
https://shop.perfectketo.com/products/keto-nootropics

- 47. The Accused Products further infringe at least claim 4 of the '462 Patent, which depends from claim 1, in the exemplary manner shown below.
  - 1. A composition for inducing ketosis, suppressing appetite, or promoting weight loss in a mammal, comprising therapeutically effective amounts of:

at least one medium chain fatty acid or ester thereof; and

- a beta-hydroxybutyrate monomer salt mixture comprising a plurality of beta-hydroxybutyrate monomer salts with at least two beta-hydroxybutyrate monomer salts selected from the group consisting of sodium beta-hydroxybutyrate, potassium beta-hydroxybutyrate, calcium beta-hydroxybutyrate, magnesium beta-hydroxybutyrate, lithium beta-hydroxybutyrate, arginine beta-hydroxybutyrate, lysine beta-hydroxybutyrate, histidine beta-hydroxybutyrate, ornithine beta-hydroxybutyrate, creatine beta-hydroxybutyrate, agmatine beta-hydroxybutyrate, and citrulline beta-hydroxybutyrate.
- 4. The composition of claim 1, wherein the beta-hydroxybutyrate monomer salt mixture comprises at least three of sodium beta-hydroxybutyrate, potassium beta-hydroxybutyrate, calcium beta-hydroxybutyrate, or magnesium beta-hydroxybutyrate.

<sup>&#</sup>x27;462 Patent, claim 4.



https://shop.perfectketo.com/products/keto-nootropics

- 48. Defendants have directly infringed at least claim 4 of the '462 Patent in the United States by making, using, offering for sale, selling, and/or importing the Accused Products in violation of 35 U.S.C. § 271(a). As such, Defendants are liable for infringement of the '462 Patent under 35 U.S.C. § 271(a).
- 49. Defendants are on notice of their infringement of the '462 Patent having received actual notice of its infringement from the Plaintiffs.
- 50. Defendants have willfully infringed the '462 Patent with knowledge of the '462 Patent or were willfully blind to the '462 Patent and the risk of the Defendants' infringement.
- 51. Defendants' acts of infringement have caused damage to Plaintiffs. Plaintiffs are therefore entitled to recover damages sustained as a result of Defendants' wrongful acts in an amount that is to be proven at trial.

## COUNT IV – INFRINGEMENT OF U.S. PATENT NO. 10,292,952

- 52. Plaintiffs incorporate all of the allegations of the preceding paragraphs as if fully set forth herein.
- 53. On May 21, 2019, the '952 Patent, titled "Mixed Salt Compositions for Maintaining or Restoring Electrolyte Balance While Producing Elevated and Sustained Ketosis" was duly and legally issued. A true and correct copy of the '952 Patent is attached as Exhibit D.
  - 54. AGS is the owner of the '952 Patent.
- 55. Defendants make, use, offer for sale, sell, and distribute ketone supplement products that practice the invention of the '952 Patent (the "Accused Products") including exemplary products sold by Defendants as "Exogenous Ketones Drink Mix," "Perform: Keto Pre-Workout Drink," and "Keto Nootropic" exogenous ketone supplement products.
  - 56. Exemplary claim 19 of the '952 Patent is reproduced below:
    - 19. A composition for maintaining or restoring electrolyte balance while promoting or sustaining ketosis in a mammal, the composition comprising:
      - a beta-hydroxybutyrate mixed salt formulated from a plurality of different cations and a single anion, wherein the single anion is beta-hydroxybutyrate, and wherein other anions are omitted from the beta-hydroxybutyrate mixed salt, the cations being formulated so as to provide a biologically balanced set of cationic electrolytes upon administration to a mammal,

the beta-hydroxybutyrate mixed salt comprising at least three salts selected from the group consisting of:

10-70% by weight of sodium beta-hydroxybutyrate;

10-70% by weight of potassium beta-hydroxybutyrate;

10-70% by weight of calcium beta-hydroxybutyrate; and

10-70% by weight of magnesium beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate mixed salt is in solid and/or powder form.

'952 Patent, claim 19.

- 57. One or more Accused Products infringe at least claim 19 of the '952 Patent in the exemplary manner described below.
- 58. To the extent the preamble of claim 19 is limiting, the Accused Products meet the preamble of claim 19 as set forth below:
  - 19. A composition for maintaining or restoring electrolyte balance while promoting or sustaining ketosis in a mammal, the composition comprising:

a beta-hydroxybutyrate mixed salt formulated from a plurality of different cations and a single anion, wherein the single anion is beta-hydroxybutyrate, and wherein other anions are omitted from the beta-hydroxybutyrate mixed salt, the cations being formulated so as to provide a biologically balanced set of cationic electrolytes upon administration to a mammal,

the beta-hydroxybutyrate mixed salt comprising at least three salts selected from the group consisting of:

10-70% by weight of sodium beta-hydroxybutyrate;

10-70% by weight of potassium beta-hydroxybutyrate;

10-70% by weight of calcium beta-hydroxybutyrate; and

10-70% by weight of magnesium beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate mixed salt is in solid and/or powder form.

'952 Patent, claim 19.

- Made to: Help reach ketosis, maintain energy levels, curb appetite, hydrate, and minimize keto flu symptoms.
- Sweetened with monk fruit for balanced sweetness
- Added electrolytes for optimal hydration
- Completely clean -- no artificial sweeteners or junk



**Exogenous Ketones Drink Mix** 

https://shop.perfectketo.com/products/keto-drink-mix

- 59. The Accused Products further meet the limitations of claim 19 as set forth below:
  - 19. A composition for maintaining or restoring electrolyte balance while promoting or sustaining ketosis in a mammal, the composition comprising:

a beta-hydroxybutyrate mixed salt formulated from a plurality of different cations and a single anion, wherein the single anion is betahydroxybutyrate, and wherein other anions are omitted from the beta-hydroxybutyrate mixed salt, the cations being formulated so as to provide a biologically balanced set of cationic electrolytes upon administration to a mammal,

the beta-hydroxybutyrate mixed salt comprising at least three salts selected from the group consisting of:

10-70% by weight of sodium beta-hydroxybutyrate;

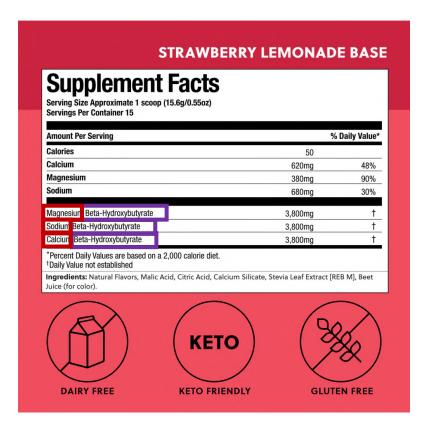
10-70% by weight of potassium beta-hydroxybutyrate;

10-70% by weight of calcium beta-hydroxybutyrate; and

10-70% by weight of magnesium beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate mixed salt is in solid and/or powder form.

'952 Patent, claim 19.



**Exogenous Ketones Drink Mix** 

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60. The Accused Products further meet the limitations of claim 19 as set forth below:

19. A composition for maintaining or restoring electrolyte balance while promoting or sustaining ketosis in a mammal, the composition comprising:

a beta-hydroxybutyrate mixed salt formulated from a plurality of different cations and a single anion, wherein the single anion is beta-hydroxybutyrate, and wherein other anions are omitted from the beta-hydroxybutyrate mixed salt, the cations being formulated so as to provide a biologically balanced set of cationic electrolytes upon administration to a mammal.

the beta-hydroxybutyrate mixed salt comprising at least three salts selected from the group consisting of:

### 10-70% by weight of sodium beta-hydroxybutyrate;

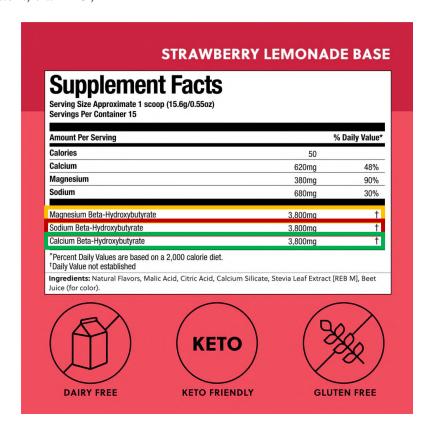
10-70% by weight of potassium beta-hydroxybutyrate;

10-70% by weight of calcium beta-hydroxybutyrate; and

10-70% by weight of magnesium beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate mixed salt is in solid and/or powder form.

'952 Patent, claim 19;



## **Exogenous Ketones Drink Mix**

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- 61. The Accused Products further meet the limitations of claim 19 as set forth below:
  - 19. A composition for maintaining or restoring electrolyte balance while promoting or sustaining ketosis in a mammal, the composition comprising:

a beta-hydroxybutyrate mixed salt formulated from a plurality of different cations and a single anion, wherein the single anion is beta-hydroxybutyrate, and wherein other anions are omitted from the beta-hydroxybutyrate mixed salt, the cations being formulated so as to provide a biologically balanced set of cationic electrolytes upon administration to a mammal,

the beta-hydroxybutyrate mixed salt comprising at least three salts selected from the group consisting of:

10-70% by weight of sodium beta-hydroxybutyrate;

10-70% by weight of potassium beta-hydroxybutyrate;

10-70% by weight of calcium beta-hydroxybutyrate; and

10-70% by weight of magnesium beta-hydroxybutyrate,

wherein the beta-hydroxybutyrate mixed salt is in solid and/or powder form.

'952 Patent, claim 19;



**Exogenous Ketones Drink Mix** 

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- 62. Defendants have directly infringed at least claim 19 of the '952 Patent in the United States by making, using, offering for sale, selling, and/or importing the Accused Products in violation of 35 U.S.C. § 271(a). As such, Defendants are liable for infringement of the '952 Patent under 35 U.S.C. § 271(a).
- 63. Defendants are on notice of the '952 Patent having received actual notice of its infringement from the Plaintiffs.
- 64. Defendants' acts of infringement have caused damage to Plaintiffs. Plaintiffs are therefore entitled to recover damages sustained as a result of Defendants' wrongful acts in an amount that is to be proven at trial.

## COUNT V – INFRINGEMENT OF U.S. PATENT NO. 11,020,362

- 65. Plaintiffs incorporate all of the allegations of the preceding paragraphs as if fully set forth herein.
- 66. On June 1, 2021, the '362 Patent, titled "Beta-hydroxybutyrate Mixed Salt Compositions and Methods of Use" was duly and legally issued. A true and correct copy of the '362 Patent is attached as Exhibit E.
  - 67. AGS is the owner of the '362 Patent.
- 68. Defendants make, use, offer for sale, sell, and distribute ketone supplement products that practice the invention of the '362 Patent (the "Accused Products") including exemplary products sold by Defendants as "Exogenous Ketones Drink Mix" exogenous ketone supplement products.
  - 69. Exemplary claim 1 of the '362 Patent is reproduced below:
    - 1. A composition for increasing blood ketone level in a subject, comprising:
      - at least three beta-hydroxybutyrate salts selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate;

wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'362 Patent, claim 1.

- 70. One or more Accused Products infringe at least claim 1 of the '362 Patent in the exemplary manner described below.
- 71. To the extent the preamble of claim 1 of the '362 Patent is limiting, the Accused Products meet the preamble of claim 1 of the '362 Patent as set forth below:
  - 1. A composition for increasing blood ketone level in a subject, comprising:

at least three beta-hydroxybutyrate salts selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate;

wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'362 Patent, claim 1.

- Made to: Help reach ketosis, maintain energy levels, curb appetite, hydrate, and minimize keto flu symptoms.
- Sweetened with monk fruit for balanced sweetness
- Added electrolytes for optimal hydration
- Completely clean -- no artificial sweeteners or junk

## **Exogenous Ketones Drink Mix**

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- 72. The Accused Products further meet the limitations of claim 1 of the '362 Patent as set forth below:
  - 1. A composition for increasing blood ketone level in a subject, comprising:

## at least three beta-hydroxybutyrate salts selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate;

wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

<sup>&#</sup>x27;362 Patent, claim 1.



**Exogenous Ketones Drink Mix** 

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- 73. The Accused Products further meet the limitations of claim 1 of the '362 Patent as set forth below:
  - 1. A composition for increasing blood ketone level in a subject, comprising:

at least three beta-hydroxybutyrate salts selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

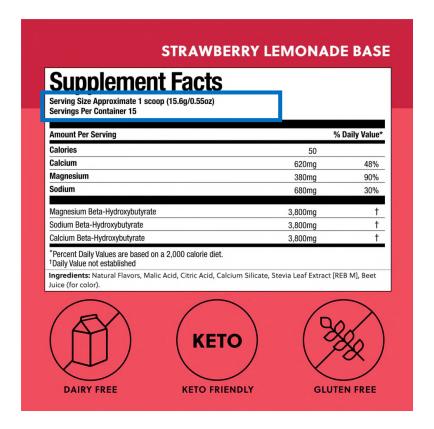
calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate;

wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'362 Patent, claim 1.



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- 74. The Accused Products further meet the limitations of claim 1 of the '362 Patent as set forth below:
  - 1. A composition for increasing blood ketone level in a subject, comprising:

at least three beta-hydroxybutyrate salts selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

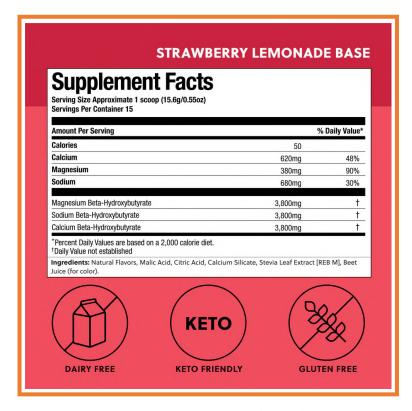
calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate;

wherein the composition is in solid and/or powder form,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

<sup>&#</sup>x27;362 Patent, claim 1.



**Exogenous Ketones Drink Mix** 

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- 75. Defendants have directly infringed claim 1 of the '362 Patent in the United States by making, using, offering for sale, selling, and/or importing the Accused Products in violation of 35 U.S.C. § 271(a). As such, Defendants are liable for infringement of the '362 Patent under 35 U.S.C. § 271(a).
- 76. Defendants are on notice of their infringement of the '362 Patent having received actual notice of its infringement from the Plaintiffs.
- 77. Defendants have willfully infringed the '362 Patent with knowledge of the '362 Patent or was willfully blind to the '362 Patent and the risk of the Defendants' infringement.
- 78. Defendants' acts of infringement have caused damage to Plaintiffs. Plaintiffs are therefore entitled to recover damages sustained as a result of Defendants' wrongful acts in an amount that is to be proven at trial.

## COUNT VI – INFRINGEMENT OF U.S. PATENT NO. 11,241,403

- 79. Plaintiffs incorporate all of the allegations of the preceding paragraphs as if fully set forth herein.
- 80. On February 8, 2022, the '403 Patent, titled "Beta-hydroxybutyrate Mixed Salt Compositions and Methods of Use" was duly and legally issued. A true and correct copy of the '403 Patent is attached as Exhibit F.
  - 81. AGS is the owner of the '403 Patent.
- 82. Defendants make, use, offer for sale, sell, and distribute ketone supplement products that practice the invention of the '403 Patent (the "Accused Products") including exemplary products sold by Defendants as "Exogenous Ketones Drink Mix" and "Keto BHB Capsules" exogenous ketone supplement products.
  - 83. Exemplary claim 13 of the '403 Patent is reproduced below:
    - 13. A composition for increasing blood ketone level in a subject, comprising:

at least one beta-hydroxybutyrate salts selected from:

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate; and

at least one other beta-hydroxybutyrate salt selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate;

magnesium beta-hydroxybutyrate; and

amino acid salts of beta-hydroxybutyrate,

wherein the composition comprises a greater total weight of calcium and magnesium beta-hydroxybutyrate salts than a total weight of sodium and potassium beta-hydroxybutyrate salts,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'403 Patent, claim 13.

- 84. One or more Accused Products infringe at least claim 13 of the '403 Patent in the exemplary manner described below.
- 85. To the extent the preamble of claim 13 of the '403 Patent is limiting, the Accused Products meet the preamble of claim 13 of the '403 Patent as set forth below:
  - 13. A composition for increasing blood ketone level in a subject, comprising:

at least one beta-hydroxybutyrate salts selected from:

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate; and

at least one other beta-hydroxybutyrate salt selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate;

magnesium beta-hydroxybutyrate; and

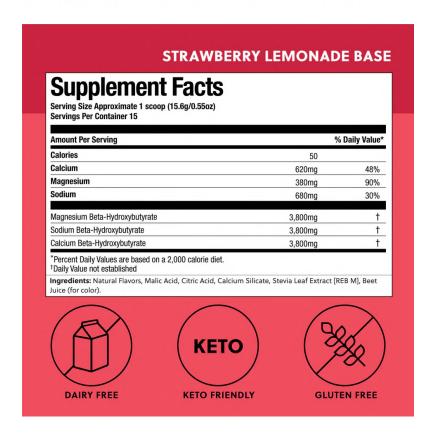
amino acid salts of beta-hydroxybutyrate,

wherein the composition comprises a greater total weight of calcium and magnesium beta-hydroxybutyrate salts than a total weight of sodium and potassium beta-hydroxybutyrate salts,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'403 Patent, claim 13.

- ✓ Made to: Help reach ketosis, maintain energy levels, curb appetite, hydrate, and minimize keto flu symptoms.
- Sweetened with monk fruit for balanced sweetness
- Added electrolytes for optimal hydration
- Completely clean -- no artificial sweeteners or junk



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- 86. The Accused Products further meet the limitations of claim 13 of the '403 Patent as set forth below:
  - 13. A composition for increasing blood ketone level in a subject, comprising:

at least one beta-hydroxybutyrate salts selected from:

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate; and

at least one other beta-hydroxybutyrate salt selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate;

magnesium beta-hydroxybutyrate; and

amino acid salts of beta-hydroxybutyrate,

wherein the composition comprises a greater total weight of calcium and magnesium beta-hydroxybutyrate salts than a total weight of sodium and potassium beta-hydroxybutyrate salts,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'403 Patent, claim 13.

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- 87. The Accused Products further meet the limitations of claim 13 of the '403 Patent as set forth below:
  - 13. A composition for increasing blood ketone level in a subject, comprising:

at least one beta-hydroxybutyrate salts selected from:

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate; and

at least one other beta-hydroxybutyrate salt selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

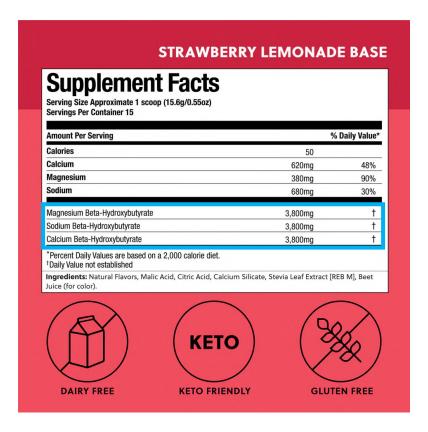
calcium beta-hydroxybutyrate;

magnesium beta-hydroxybutyrate; and amino acid salts of beta-hydroxybutyrate,

wherein the composition comprises a greater total weight of calcium and magnesium beta-hydroxybutyrate salts than a total weight of sodium and potassium beta-hydroxybutyrate salts,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

'403 Patent, claim 13.



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88. The Accused Products further meet the limitations of claim 13 of the '403 Patent as set forth below:

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13. A composition for increasing blood ketone level in a subject, comprising:
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at least one beta-hydroxybutyrate salts selected from:

calcium beta-hydroxybutyrate; and

magnesium beta-hydroxybutyrate; and

at least one other beta-hydroxybutyrate salt selected from:

sodium beta-hydroxybutyrate;

potassium beta-hydroxybutyrate;

calcium beta-hydroxybutyrate;

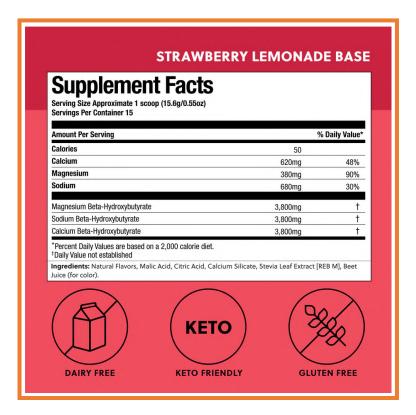
magnesium beta-hydroxybutyrate; and

amino acid salts of beta-hydroxybutyrate,

wherein the composition comprises a greater total weight of calcium and magnesium beta-hydroxybutyrate salts than a total weight of sodium and potassium beta-hydroxybutyrate salts,

wherein the composition is free of medium chain fatty acids having 6 to 12 carbons and glycerides or other esters thereof.

<sup>&#</sup>x27;403 Patent, claim 13.



**Exogenous Ketones Drink Mix** 

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- 89. Defendants have directly infringed claim 1 of the '403 Patent in the United States by making, using, offering for sale, selling, and/or importing the Accused Products in violation of 35 U.S.C. § 271(a). As such, Defendants are liable for infringement of the '403 Patent under 35 U.S.C. § 271(a).
- 90. Defendants are on notice of its infringement of the '403 Patent having received actual notice of its infringement from the Plaintiffs.
- 91. Defendants have willfully infringed the '403 Patent with knowledge of the '403 Patent or were willfully blind to the '403 Patent and the risk of the Defendants' infringement.

92. Defendants' acts of infringement have caused damage to Plaintiffs. Plaintiffs are therefore entitled to recover damages sustained as a result of Defendants' wrongful acts in an amount that is to be proven at trial.

## **PRAYER FOR RELIEF**

Wherefore, Plaintiffs respectfully pray that the Court enter judgment in its favor and award the following relief against Defendants:

- A. A judgment that Defendants have infringed one or more claims of the Asserted USF Patents and the Asserted AGS Patents literally and/or under the doctrine of equivalents;
  - B. An award of damages pursuant to 35 U.S.C. § 284;
- C. Entry of an injunction against further infringement of the Asserted USF Patents and the Asserted AGS Patents;
- D. A judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and an award of the Plaintiffs' reasonable attorneys' fees in this litigation;
  - E. An award of prejudgment and post-judgment interest on their damages;
  - F. An award of costs; and
  - G. Any such other and further relief as the Court deems proper.

## **DEMAND FOR JURY TRIAL**

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs demand a jury trial on all matters triable to a jury.

Respectfully submitted,

By: /s/ Kathleen M. Miller

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Dated: November 22, 2022

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Dated: November 22, 2022 10452379/22680.00001

Attorneys for Defendants University of South Florida Board of Trustees and University of South Florida Research Foundation, Inc.

By: /s/Bindu A. Palapura

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