**UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF GEORGIA**
**ATLANTA DIVISION**

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|---|---|
| JOHN'S LONE STAR DISTRIBUTION, INC. d/b/a LONE STAR DISTRIBUTION and PURUS LABS, INC.,<br><br>Plaintiffs,<br><br>v.<br><br>THERMOLIFE INTERNATIONAL, LLC,<br><br>Defendant. | Civil Action No.: 13-cv-1857-SCJ |

**PLAINTIFFS' FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL**

NOW COME Plaintiffs John's Lone Star Distribution, Inc. d/b/a Lone Star Distribution (hereinafter "Lone Star") and Purus Labs, Inc. ("Purus"), and, for their Complaint, allege as follows:

**THE PARTIES**

1. Plaintiff John's Lone Star Distribution, Inc. d/b/a Lone Star Distribution (hereinafter "Lone Star") is a corporation organized and existing under the laws of the State of Texas with a principal place of business at 4000 Royal Drive, Suite 200, Kennesaw, Georgia 30144.

2. Plaintiff Purus Labs, Inc. (hereinafter "Purus") is a corporation organized and existing under the laws of the State of Texas with a principal place of business at 11370 Pagemill Road in Dallas, Texas 75243.

3. Defendant ThermoLife International, LLC, (hereinafter "ThermoLife"), on information and belief, is a corporation organized under the laws of the State of Arizona, with a principal place of business at 1811 Ocean Front Walk in Venice, CA 90291.

## JURISDICTION AND VENUE

4. This Court has exclusive jurisdiction over the subject matter of this Complaint pursuant to 28 U.S.C. § 1331 and 1338(a), whereas Lone Star's and Purus' claims arise under an act of Congress relating to patents.

5. This Complaint is further brought pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*. as an actual controversy exists under 28 U.S.C. §§ 2201 and 2202.

6. This Court has personal jurisdiction over ThermoLife whereas ThermoLife regularly conducts business within the Northern District of Georgia.

7. Venue is appropriate under 28 U.S.C. § 1391(b), (c) and 1400(b).

## COUNT I

## FOR DECARATORY JUDGMENT OF NON-INFRINGEMENT

8. Lone Star and Purus incorporate the allegations set forth in paragraphs 1 through 7 above by reference as if fully set forth herein.

9. On information and belief, ThermoLife is the owner by assignment of United States Patent No. 8,455,531 to Ronald Kramer and Alexander Nikolaidis,

which issued on June 4, 2013, entitled *Amino Acid Compounds*, hereinafter "the '531 patent." A copy of the '531 patent is attached hereto as Exhibit A.

10. On or about September 6, 2012, ThermoLife, through counsel, transmitted a cease and desist letter to Purus and, alleging, *inter alia*, that Purus infringes the claims of then pending U.S. Patent Application Publication No. 20110313042, hereinafter "the '042 publication", from which the '531 patent claims priority.

11. On or about December 13, 2012, ThermoLife, through counsel, transmitted a cease and desist letter to Lone Star, alleging, *inter alia*, that Lone Star infringes the claims of the '042 and publication.

12. On or about December 14, 2012, ThermoLife, through counsel, sent another cease and desist letter to Purus, again alleging, *inter alia*, that Purus infringes the claims of the '042 publication.

13. On or about May 29, 2013, ThermoLife, through counsel, sent another cease and desist letter to Lone Star, alleging, *inter alia*, that Lone Star infringes the claims of U.S. Patent Application Serial No. 13/038,537, which previously published as the '042 publication, and stated "ThermoLife plans to sue [Lone Star], as well as all the companies mentioned above, for infringement of these patents after [the '531 patent issues], to potentially include a preliminary injunction as well

as seeking pre-patent issuance damages, in addition to attorneys' fees and treble damages for willful infringement."

14. At all times relevant hereto, Lone Star and Purus have a reasonable apprehension of being sued for patent infringement by ThermoLife.

15. At all times relevant hereto, Lone Star's and Purus' products have not directly infringed and do not directly infringe any or all claims of the '531 patent under 35 U.S.C. §271(a).

16. Lone Star and Purus have not actively induced and do not actively induce infringement of any or all claims of the '531 patent under 35 U.S.C. § 271 (b).

17. Lone Star and Purus have not contributed to and do not contribute to infringement of any or all of the claims of the '531 patent under 35 U.S.C. § 271 (c).

18. Lone Star and Purus are therefore entitled to a declaratory judgment that Lone Star's and Purus' products do not directly or indirectly infringe any or all of the claims of the '531 patent and to such further injunctive relief as may be just and proper.

## COUNT II

## FOR DECLARATORY JUDGMENT OF PATENT INVALIDITY

19. Lone Star and Purus incorporate the allegations set forth in paragraphs 1 through 18 above by reference as if fully set forth herein.

20. The '531 patent is invalid for failure to comply with the statutory provisions for patentability and validity set forth Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, 112, 115, 116 and 256, for the following reasons:

a. The alleged invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, more than one year prior to the date of the application for a patent in the United States.

b. The alleged invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

c. The patentees did not themselves invent the subject matter sought to be patented.

d. Before the alleged invention by the patentees the alleged invention was made in this country by another who had not abandoned, suppressed or concealed it.

e. The alleged invention was obvious at the time of the invention to a person having ordinary skill in the art.

21. Lone Star and Purus are therefore entitled to a declaratory judgment that some or all of the claims of the '531 patent are invalid and to such further relief as may be just and proper.

**COUNT III**

**FOR DECLARATORY JUDGMENT OF NON-INFRINGMENT**

22. Lone Star and Purus incorporate the allegations set forth in paragraphs 1 through 21 above by reference as if fully set forth herein.

23. On information and belief, ThermoLife is the owner by assignment of United States Patent No. 8,466,187 to Ronald Kramer and Alexander Nikolaidis, which issued on June 18, 2013, entitled *Amino Acid Compounds*, hereinafter "the '187 patent." A copy of the '187 patent is attached hereto as Exhibit B.

24. On or about September 6, 2012, ThermoLife, through counsel, transmitted a cease and desist letter to Purus and, alleging, *inter alia*, that Purus infringes the claims of then pending U.S. Patent Application Publication No. 20110313043, hereinafter "the '043 publication", from which the '187 patent claims priority.

25. On or about December 13, 2012, ThermoLife, through counsel, transmitted a cease and desist letter to Lone Star, alleging, *inter alia*, that Lone Star infringes the claims of the '043 publication.

26. On or about December 14, 2012, ThermoLife, through counsel, sent another cease and desist letter to Purus, again alleging, *inter alia*, that Purus infringes the claims of the '043 publication.

27. On or about May 29, 2013, ThermoLife, through counsel, sent another cease and desist letter to Lone Star, alleging, *inter alia*, that Lone Star infringes the claims of U.S. Patent Application Serial No. 13/038,615, which previously published as the '043 publication, and stated "ThermoLife plans to sue [Lone Star], as well as all the companies mentioned above, for infringement of these patents after [the '187 patent issues], to potentially include a preliminary injunction as well as seeking pre-patent issuance damages, in addition to attorneys' fees and treble damages for willful infringement."

28. At all times relevant hereto, Lone Star and Purus have a reasonable apprehension of being sued for patent infringement by ThermoLife.

29. At all times relevant hereto, Lone Star's and Purus' products have not directly infringed and do not directly infringe any or all claims of the '187 patent under 35 U.S.C. §271(a).

30. Lone Star and Purus have not actively induced and do not actively induce infringement of any or all claims of the '187 patent under 35 U.S.C. § 271 (b).

31. Lone Star and Purus have not contributed to and do not contribute to infringement of any or all of the claims of the '187 patent under 35 U.S.C. § 271 (c).

32. Lone Star and Purus are therefore entitled to a declaratory judgment that Lone Star's and Purus' products do not directly or indirectly infringe any or all of the claims of the '187 patent and to such further injunctive relief as may be just and proper.

**COUNT IV**

**FOR DECLARATORY JUDGMENT OF PATENT INVALIDITY**

33. Lone Star and Purus incorporate the allegations set forth in paragraphs 1 through 32 above by reference as if fully set forth herein.

34. Lone Star and Purus have not contributed to and do not contribute to infringement of any or all of the claims of the '187 patent under 35 U.S.C. § 271 (c).

35. Lone Star and Purus are therefore entitled to a declaratory judgment that Lone Star's and Purus' products do not directly or indirectly infringe any or all

of the claims of the '187 patent and to such further injunctive relief as may be just and proper.

**COUNT V**

**INEQUITABLE CONDUCT**

36. Lone Star and Purus incorporate the allegations set forth in paragraphs 1 through 35 above by reference as if fully set forth herein.

37. On or about September 6, 2012, ThermoLife, through counsel, transmitted a cease and desist letter to Purus and, alleging, *inter alia*, that Purus infringes the claims of the '042 and '043 publications.

38. On or about December 13, 2012, ThermoLife, through counsel, transmitted a cease and desist letter to Lone Star and, alleging, *inter alia*, that Lone Star infringes the claims of the '042 and '043 publications.

39. The application for the '187 patent, which published as the '043 publication, was filed on March 2, 2011, and is a continuation-in-part of U.S. Patent No. 8,034,836, filed on December 17, 2008, which is a continuation of U.S. Patent No. 7,777,074, filed on December 4, 2007, which claims priority to U.S. Provisional Patent Application 60/973,229, filed September 18, 2007.

39. On or about December 20, 2012, during the pendency of the applications for the '531 and '187 patents, respectively, a letter was transmitted to

ThermoLife's patent prosecution counsel Pacer K. Udall, Esq., providing a copy of U.S. Patent No. 5,543,430 to Kaesemeyer, hereinafter "*Kaesemeyer*".

40. *Kaesemeyer* published on August 6, 1996, which was more than one year prior to the earliest priority date for the '187 patent and, therefore, qualifies as a prior art reference under 35 U.S.C. § 102(b).

41. In the December 20, 2012 letter, the following passages from *Kaesemeyer* were brought to Mr. Udall's attention:

> ***A therapeutic mixture comprising a mixture of L-arginine and an agonist of nitric oxide synthase, namely nitroglycerin, is disclosed for the treatment of diseases related to vasoconstriction***, wherein the vasoconstriction is relieved by stimulating the constitutive form of nitric oxide synthase (cNOS) to produce native nitric oxide (NO). The native NO having superior beneficial effect when compared to exogenous NO produced by a L-arginine independent pathway in terms of the ability to reduce clinical endpoints and mortality.

[Emphasis added.] *Kaesemeyer*, Abstract.

> ***Yet another embodiment is a method for treating hypertension in a subject by vasodilation comprising: selecting a hypertensive subject; administering to said subject an anti-hypertensive formulation comprising a mixture of L-arginine and nitroglycerin***; obtaining periodic blood pressure measurements on the subject; and; continuing administration of the anti-hypertensive formulation until a desirable blood pressure is detected in the subject.

[Emphasis added.] *Kaesemeyer*, col. 4, lns. 45-50.

> ***Combining L-arginine and nitroglycerin may also result in a combined arterial and venous dilatory effect***. Used alone nitroglycerin is principally a venodilator and causes rapid increase in heart beat due to its venous pooling, while L-arginine on the other hand when used alone is principally an arterial dilator. Therefore,

> combining the two results in balanced arterial and venodilatory effect which counter balances the tendencies of one or the other to produce tachycardia which is adverse to ischemia in an evolving myocardial infarction.

(Emphasis added.) *Kaesemeyer*, col. 8, lns.

Claims 1, 2, 4 and 5, for example, of *Kaesemeyer* are as follows:

> 1. A method of treating a disease condition in a subject by ***vasodilation*** or vasorelaxation comprising:
>
> selecting a subject;
>
> mixing ***L-arginine and a venous dilator***, said venous dilator being different than L-arginine;
>
> administering to said subject a ***formulation comprising said mixture***; obtaining periodic indicators of vasorelaxations for the subject; and;
>
> continuing administration of the formulation until a desirable state of vasorelaxtion is obtained.
>
> 2. The method of claim 1, wherein the formulation is administered intravenously, buccal, intracoronary, intramuscularly, topically, intranasally, rectally, sublingually, orally, subcutaneously, or by patch.
>
> 4. The method of claim 3, wherein said ***venous dilator is an exogenous source of nitric oxide***.
>
> 5. The method of claim 4, wherein said ***exogenous source of nitric oxide is nitroglycerin***.

42. The specification of the '043 publication, now the '187 patent, states the following:

> As used herein, ***"Nitrate" is a term used in its broadest sense*** and may refer to an Nitrate in its many different chemical forms including a salt of Nitric Acid, a single administration Nitrate, its physiologically active salts or esters, its combinations with its various salts, its tautomeric, polymeric and/or isomeric forms, its analog

> forms, and/or its derivative forms. Nitrate comprises, by way of non-limiting example, many different chemical forms including dinitrate and trinitrate. Nitrates may be salts, or mixed salts, of Nitric Acid ($HNO_3$) and comprise one Nitrogen atom and three Oxygen atoms ($NO_3$). For the exemplary purposes of this disclosure, Nitrate may comprise salts of Nitrate such as sodium nitrate, potassium nitrate, barium nitrate, calcium nitrate, and the like. For the exemplary purposes of this disclosure, Nitrate may include mixed salts of Nitrate such as nitrate orotate, and the like. ***Additionally, for the exemplary purposes of this disclosure, Nitrate may comprise nitrate esters such as nitroglycerine, and the like.*** Furthermore, for the exemplary purposes of this disclosure, nitrates that are commonly used in supplement industry are appropriate sources of nitrates, such as juice, extract, powder and the like of Cabbage, Spinach, Beetroot, Artichoke, Asparagus, Broad Bean, Eggplant, Garlic, Onion, Green Bean, Mushroom, Pea, Pepper, Potato, Summer Squash, Sweet Potato, Tomato, Watermelon, Broccoli, Carrot, Cauliflower, Cucumber, Pumpkin, Chicory, Dill, Turnip, Savoy Cabbage, Celeriac, Chinese Cabbage, Endive, Fennel, Kohlrabi, Leek, Parsley, Celery, Cress, Chervil, Lettuce, Rocket (Rucola), and the like.

[Emphasis added.] The '043 publication, p. 3-4, ¶ [0040].

43. At the time of the December 20, 2012 letter, the three pending claims of the '042 publication read as follows:

> 1. An amino acid composition comprising:
>
> at least one constituent selected from the group consisting of a nitrate, a nitrite, and both; and
>
> at least one constituent amino acid selected from the group consisting of Arginine, Agmatine, Beta Alanine, Citrulline, Creatine, Glutamine, L-Histidine, Isoleucine, Leucine, Norvaline, Ornithine, Valine, Aspartic Acid, Cysteine, Glycine, Lysine, Methionine, Proline, Tyrosine, and Phenylalanine.
>
> 2. A method for increasing bioabsorption of Amino Acids in a human or animal, the method comprising administering to the human or animal a pharmaceutically effective amount of an amino acid

> composition comprising at least one constituent selected from the group consisting of a nitrate, a nitrite, and both, and at least one constituent amino acid selected from the group consisting of Arginine, Agmatine, Beta Alanine, Citrulline, Creatine, Glutamine, L-Histidine, Isoleucine, Leucine, Norvaline, Ornithine, Valine, Aspartic Acid, Cysteine, Glycine, Lysine, Methionine, Proline, Tyrosine, and Phenylalanine.
>
> 3. A method for increasing vasodilative characteristics of Amino Acids in a human or animal, the method comprising administering to the human or animal a pharmaceutically effective amount of an amino acid composition comprising at least one constituent selected from the group consisting of a nitrate, a nitrite, and both, and at least one constituent amino acid selected from the group consisting of Arginine, Agmatine, Beta Alanine, Citrulline, Creatine, Glutamine, L-Histidine, Isoleucine, Leucine, Norvaline, Ornithine, Valine, Aspartic Acid, Cysteine, Glycine, Lysine, Methionine, Proline, Tyrosine, and Phenylalanine.

44. The December 20, 2012 letter stated, "[c]learly, *Kaesemeyer* teaches each and every element of Claims 1 and 3 of the '042 publication. Accordingly, Claims 1 and 3 are invalid under 35 U.S.C. § 102(b) in view of *Kaesemeyer*. Thus, *Kaesemeyer* is a reference that is material to patentability of the '042 publication."

45. The December 20, 2012 letter further stated, "[l]ikewise, **with respect to the '043 publication, the claims are virtually identical to those of the '042 publication and, therefore, are invalid**." [Emphasis added.]

46. The December 20, 2012 letter also referred to 37 C.F.R § 1.56 and provided the following passage therefrom:

> Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information

> known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned… However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct.

47. On December 24, 2012, in response to the December 20, 2012 letter, Applicants, through counsel, filed an amendment and amended Claims 1 and 3 of the '043 publication for reasons of patentability by deleting the amino acid "arginine" from the respective Markush groupings of various amino acids originally presented in these claims.

48. In the amendment filed on December 24, 2012, Applicants, through counsel, stated the following to the United States Patent and Trademark Office:

> Attorneys representing third parties emailed counsel for applications on Friday, December 21, 2012 at 4:55 pm EST patent 5,543,430 set forth in the attached IDS. Applicants and applicants' counsel were not aware of this patent until it was emailed. Applicants are petitioning to withdraw the application form issuance and are submitting the reference *so that they can never be accused of breaching the duty to disclose information*. [Emphasis added.]

49. Although two information disclosure statements were filed in the application for the '187 patent after December 20, 2012, *Kaesemeyer* was not included in either information disclosure statement and is not of record in the file history of the '187 patent.

50. At all times relevant hereto, Applicants' patent counsel knew *Kaesmeyer* was material to patentability of the claims of the '187 patent.

51. The '187 patent includes 60 method claims, generally categorized into three groups: a) methods for increasing athletic performance in a human or animal; b) methods for increasing distribution of amino acids to muscles in a human or animal; and c) methods for increasing solubility of amino acids in a human or animal.

52. Claim 2 of the '187 patent issued as follows:

> 2. A method for increasing distribution of Amino Acids to muscles in a human or animal, the method comprising administering to the human or animal a pharmaceutically effective amount of an amino acid composition comprising at least one constituent selected from the group consisting of a nitrate, a nitrite, and both, and Arginine.

53. Claim 3 of the '187 patent issued as follows:

> 3. A method for increasing solubility of Amino Acids in a human or animal, the method comprising administering to a human or animal a pharmaceutically effective amount of an amino acid composition comprising at least one constituent selected form the group consisting of a nitrate, a nitrite, and both, and arginine.

54. At all times relevant hereto, *Kaesemeyer* states the following:

> It has been discovered that combining L-arginine with nitroglycerin prior to administration overcomes the resistance of tolerance level normally established when administering nitroglycerin alone.

*Kaesemeyer*, col. 5, lns. 15-18.

> ***A therapeutic mixture comprising a mixture of L-arginine and an agonist of nitric oxide synthase, namely nitroglycerin, is disclosed for the treatment of diseases related to vasoconstriction***, wherein the vasoconstriction is relieved by stimulating the constitutive form of nitric oxide synthase (cNOS) to produce native nitric oxide (NO). The native NO having superior beneficial effect when compared to exogenous NO produced by a L-arginine independent pathway in terms of the ability to reduce clinical endpoints and mortality. [Emphasis added.]

*Id.*, Abstract.

> ***Yet another embodiment is a method for treating hypertension in a subject by vasodilation comprising: selecting a hypertensive subject; administering to said subject an anti-hypertensive formulation comprising a mixture of L-arginine and nitroglycerin***; obtaining periodic blood pressure measurements on the subject; and; continuing administration of the anti-hypertensive formulation until a desirable blood pressure is detected in the subject. [Emphasis added.]

*Id.*, col. 4, lns. 45-50.

> ***Combining L-arginine and nitroglycerin may also result in a combined arterial and venous dilatory effect***. Used alone nitroglycerin is principally a venodilator and causes rapid increase in heart beat due to its venous pooling, while L-arginine on the other hand when used alone is principally an arterial dilator. Therefore, combining the two results in balanced arterial and venodilatory effect which counter balances the tendencies of one or the other to produce tachycardia which is adverse to ischemia in an evolving myocardial infarction. [Emphasis added.]

*Id.*, col. 8, lns. 13-14.

55. At all times relevant hereto, *Kaesemeyer* teaches each and every element of Claims 2 and 3 of the '187 patent, thereby anticipating these claims under 35 U.S.C. § 102(b).

56. At all times relevant hereto, *Kaesemeyer* renders one or more claims of the '187 patent as prima facie obvious under 35 U.S.C. § 103(a) either alone or in combination of prior art of record in the file history of the '187 patent.

57. At all times relevant hereto, *Kaesemeyer* is material to patentability of one or more claims of the '187 patent.

58. At all times relevant hereto, Applicants and their patent counsel intentionally withheld disclosure of *Kaesemeyer* from the United States Patent and Trademark Office during the pendency of the application for the '187 patent.

59. At all times relevant hereto, the above recited acts constituted fraud and/or inequitable conduct in the proceedings before the United States Patent and Trademark Office curing the prosecution of the '187 patent.

60. Lone Star and Purus are therefore entitled to judgment that the '187 patent is unenforceable, a declaration that this case is exceptional in favor of Lone Star and Purus under 35 U.S.C. § 285 and that Lone Star and Purus be awarded its reasonable attorneys' fees and expenses.

## PRAYER FOR RELIEF

WHEREFORE, Lone Star and Purus pray for the following relief:

A. That Judgment be entered in favor of Lone Star and Purus and against ThermoLife on each and every count of the Complaint;

B. That Judgment be entered declaring that neither Lone Star's and Purus' products infringe the '531 patent;

C. That Judgment be entered declaring the claims of the '531 patent invalid;

D. That Judgment be entered permanently enjoining and restraining TheromoLife, its officers, agents, servants, employees and attorneys, and all others acting on behalf for, on behalf of, or in active concert or participation with any of them, from stating, implying or suggesting that Lone Star and Purus infringe the '531 patent;

E. That Judgment be entered declaring that neither Lone Star's and Purus' products infringe the '187 patent;

F. That Judgment be entered declaring the claims of the '187 patent invalid;

G. That Judgment be entered permanently enjoining and restraining TheromoLife, its officers, agents, servants, employees and attorneys, and all others acting on behalf for, on behalf of, or in active concert or participation with any of them, from stating, implying or suggesting that Lone Star and Purus infringe the '187 patent;

H. That Judgment be entered declaring the claims of the '187 patent unenforceable for inequitable conduct;

I. That Judgment be entered declaring that this case is exceptional under 35 U.S.C. § 285 and that Lone Star and Purus be awarded their reasonable attorneys' fees and expenses;

J. That Lone Star and Purus be awarded their costs in this action; and,

K. That Lone Star and Purus be awarded such other and further relief as the Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Lone Star and Purus demand a trial by jury of all issues so triable in this action.

Respectfully submitted,

Dated: June 18, 2013

By: /s/ Jeffery B. Arnold

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