Gregory B. Collins (#023158)
Jenessa G. B. Coccaro (#027090)
KERCSMAR & FELTUS PLLC
6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
Telephone: (480) 421-1001
Fax: (480) 421-1002
gbc@kflawaz.com
jbc@kflawaz.com

Attorneys for Plaintiffs Ron Kramer; Sal Abraham;
and ThermoLife International LLC

Kercsmar & Feltus PLLC
6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

| | |
|---|---|
| Ron Kramer, an Arizona resident; Sal Abraham, a Florida resident; and ThermoLife International LLC, an Arizona limited liability company,<br><br>Plaintiffs,<br><br>v.<br><br>Creative Compounds LLC, a Nevada limited liability company,<br><br>Defendant. | No.<br><br>**COMPLAINT**<br><br>(Jury Trial Demanded) |

Plaintiffs Ron Kramer, Sal Abraham, and ThermoLife International LLC, for their complaint against defendant Creative Compounds LLC, allege upon personal knowledge with respect to itself and its own acts, and upon information and belief with respect to all other matters, as follows:

## NATURE OF ACTION

1. Plaintiffs Ron Kramer and Sal Abraham (together "the Inventors") bring claims for patent infringement, inducement of patent infringement, contributory patent infringement, and false advertising against Creative Compounds LLC ("Creative Compounds"). Creative Compounds is openly violating U.S. Patent No. 7,919,533 B2

Kercsmar & Feltus PLLC
6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

("the '533 Patent"), which protects and covers the use of diiodothyroacetic acid in dietary supplements. *See* Exhibit A. Diiodothyroacetic acid is a powerful and effective compound that when used in effective amounts shifts the proportion between lean body mass and adipose tissue (fat) in favor of lean body mass in humans. It is therefore a desirable additive to dietary supplements.

2. Competition in the dietary supplement industry is fierce, with each company seeking to discover and market the next breakthrough product that will help build muscle and/or decrease fat. Faced with stiff competition and the ever-increasing desire of the market for the next great muscle building supplement, dietary supplement makers frequently copy the successful products and ingredients offered by other makers, even if protected by United States patent laws.

3. In this case, Creative Compounds has violated the '533 Patent by including diiodothyroacetic acid in dietary supplements and by inducing other supplement companies to include diiodothyroacetic acid in dietary supplement formulations.

4. On or about September 23, 2011, Creative Compounds advertised that it had acquired a supply of diiodothyroacetic acid that it could use to formulate dietary supplements for supplement companies. *See* Exhibit B.

5. Creative Compounds falsely advertised that consumers should "[b]eware of other [d]iiodothyroacetic acid products on the market that are not pure!" Creative Compounds also falsely stated that its diiodothyroacetic acid "is the most pure."

6. The Inventors bring this action to enjoin Creative Compounds from continuing to violate the '533 Patent.

7. ThermoLife brings suit to enjoin Creative Compounds from continuing to falsely advertise its products.

8. The Inventors and ThermoLife seek to recover damages, lost profits, and a reasonable royalty as well as treble damages for lost sales resulting from Defendant's

willful infringement and false advertising. In addition, Creative Compounds should be made to disgorge its illegal profits.

**PARTIES, JURISDICTION AND VENUE**

9. Plaintiff Ron Kramer is an Arizona resident. Ron Kramer is named as an inventor on the '533 Patent.

10. Plaintiff Sal Abraham is a Florida resident. Sal Abraham is named as an inventor on the '533 Patent.

11. Plaintiff ThermoLife is an Arizona limited liability company. ThermoLife's principal place of business is 3914 E. Chandler Blvd, Phoenix, Arizona 85048.

12. Defendant Creative Compounds is a Nevada limited liability company with its principle place of business in Oregon.

13. Creative Compounds ships and sells products nationwide, including in Arizona.

14. Creative Compounds advertises its products nationwide, including in Arizona.

15. The Court has jurisdiction over Plaintiff's federal claims under 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338 because this action, at least in part, is for patent infringement and arises under the patent laws of the United States, Title 35, Section 271 *et seq*. of the United States Code. This Court has jurisdiction over any Arizona state law claims asserted by the parties under principles of pendent, ancillary, and supplemental jurisdiction, 28 U.S.C. §§ 1338(b) and 1367(a).

16. This Court also has jurisdiction over this matter pursuant to 28 U.S.C. § 1332 because all parties are diverse in citizenship from ThermoLife and the amount in controversy exceeds $75,000, exclusive of interests and costs.

17. Venue is proper in this District under 28 U.S.C. § 1391(b)-(c), because a substantial part of the events or omissions giving rise to ThermoLife's claims occurred in

Kercsmar & Feltus PLLC
6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

this District. Venue is also proper in this district because Creative Compounds is subject to personal jurisdiction in this district.

## FACTUAL ALLEGATIONS

### A. ThermoLife

18. Ron Kramer ("Kramer") founded ThermoLife in 1998. Prior to founding ThermoLife, Kramer was a gym owner who had competed in bodybuilding and later promoted professional bodybuilding competitions for the International Federation of Bodybuilders.

19. Between 1994 and 1997, Kramer opened and operated a Gold's Gym in Santa Cruz, California.

20. During his time as a bodybuilder, promoter, and gym owner, Kramer discovered that many dietary supplements failed to meet any quality control standards. Often supplements were spiked with hidden ingredients and labeled incorrectly. Many were ineffective.

21. At the time ThermoLife was established, few supplements were clinically researched or field tested. Even today, relatively few supplements have been proven to work as advertised.

22. In 1998, Kramer founded ThermoLife in order to provide the public with quality proven supplements. ThermoLife is committed to selling only the purest, most effective and innovative products.

23. By relying on supposedly proprietary formulas, supplement companies often hide the ingredients in their products from consumers. Unlike other supplement companies, ThermoLife develops unique and novel products and formulas that it fully discloses to the public. In this way, ThermoLife allows consumers to know exactly what products and raw materials they consume.

Kercsmar & Feltus PLLC
6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

Kercsmar & Feltus PLLC
6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

24. By fully disclosing its formulas and relying on scientifically proven and protected formulas and ingredients, ThermoLife has taken a lead role in ending the deceptive business practices that have plagued the supplement industry.

**B. ThermoLife's '533 Patent and its Dicana Product**

25. On October 20, 2004, Ron Kramer and Sal Abraham submitted an application for a United States Patent related to the use of diiodothyroacetic acid in dietary supplements.

26. On April 5, 2011, the '533 Patent was duly and legally issued to inventors Sal Abraham and Ron Kramer. A true and correct copy of the '533 Patent is attached as Exhibit A, and incorporated herein by this reference.

27. As stated in the '533 Patent, the patent claims "a method of promoting lean body mass in human individuals having a body mass index of at least 25, comprising directly administering to the individual an effective amount of diiodothyroacetic acid."

28. The '533 Patent also claims, "A dietary supplement comprising diiodothyroacetic acid."

29. ThermoLife's top-selling Dicana product embodies the '533 Patent.

30. Dicana is sold by ThermoLife as a dietary supplement and its ingredients include diiodothyroacetic acid.

31. When used as directed, Dicana has the ability to raise Resting Metabolic Rate and may dramatically shift the proportion between lean body mass and adipose tissue (fat) in favor of lean body mass.

32. ThermoLife's supplements, including Dicana, are sold nationwide on the internet and in vitamin and dietary supplement stores such as The Vitamin Shoppe.

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6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

**C. Infringement**

33. Creative Compounds started as a compounding pharmacy in 1998. In addition to customizing compounds for prescription drugs, Creative Compounds sells and compounds dietary supplements.

34. In the dietary supplement market, ThermoLife and Creative Compounds are competitors in the sense that they vie for the same dollars from the same consumer group.

35. On or about September 22, 2011, Creative Compounds sent out a mass email marketing diiodothyroacetic acid for use in dietary supplements. A true and accurate copy of Creative Compounds mass email is attached as Exhibit B.

36. Creative Compounds mass email stated:

> "Creative Compounds is pleased to introduce ***DIACtive*** brand of diiodothyroacetic acid (DIAC), one of the most exciting dietary supplements of the decade. Having worked extensively with this novel ingredient, Creative Compounds knows all of the intricacies surrounding its pharmacology and usage. We have the unique ability to help your company properly formulate and integrate this ingredient into a top selling product on the market. Beware of other diiodiothyroacetic [sic] acid products on the market that are not pure! Beware of other products on the market that are highly diluted but sell for an extremely high price. DIACtive is the most pure, highest quality DIAC in the industry and is GUARANTEED to be the lowest price diiodothyroacetic acid in the industry."

37. Creative Compounds' mass email also included a sales sheet for its DIACtive brand of diiodothyroacetic acid. A true and accurate copy of the sales sheet is attached as Exhibit C.

38. As stated in Creative Compounds' mass email and sales sheet, Creative Compounds is offering for sale diiodothyroacetic acid for use as a dietary supplement.

39. Any dietary supplement created by Creative Compounds that includes diiodothyroacetic acid would infringe the '533 Patent (hereinafter "the Infringing Products").

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(480) 421-1001

40. In addition to offering for sale diiodothyroacetic acid as a dietary supplement, Creative Compounds is actively and/or intentionally inducing others to use and/or sell diiodothyroacetic acid in dietary supplements, in direct infringement of the '533 Patent. Creative Compounds' statement that, "We have the unique ability to help your company properly formulate and integrate this ingredient into a top selling product on the [dietary supplement] market," establishes that Creative Compounds is inducing others to infringe the '533 Patent.

41. As a member of the nutritional supplement and bodybuilding industries, Creative Compounds appreciates the scope of the '533 Patent.

42. Notwithstanding Creative Compounds' appreciation of the value and scope of the '533 Patent, Creative Compounds has sold, manufactured, imported and/or used diiodothyroacetic acid in dietary supplements.

43. Upon information and belief, Creative Compounds has manufactured and sold, and continues to manufacture and sell, diiodothyroacetic acid for use in dietary supplements.

44. Creative Compounds sells diiodothyroacetic acid for use in dietary supplements over the internet and elsewhere. Creative Compounds seeks to sell diiodothyroacetic acid for use in dietary supplements to retailers, distributors, dealers, and/or the general public, including the general public in the State of Arizona and this District. Upon information and belief, Creative Compounds has sold diiodothyroacetic acid for use in dietary supplements in the State of Arizona and this District.

45. Creative Compounds has been aware of its infringing activity since at least September 22, 2011, after Kramer emailed a Creative Compounds' employee, Corey McNeely. In response to the email, on or about September 22, 2011, Kramer received a phone call from an attorney representing Creative Compounds. On that phone call, Kramer informed Creative Compounds of its infringement.

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6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

46. Despite notice of its infringing activity, Creative Compounds has continued and continues its infringing activity to date.

47. The activities of Creative Compounds with regard to its sales, importation, manufacture and/or use of diiodothyroacetic acid for use in dietary supplements are and have been without authorization from the Inventors.

**D. Creative Compounds' False Advertising**

48. Creative Compounds September 22, 2011 mass email and sales sheet falsely advertised Creative Compounds ***DIACtive*** brand of diiodothyroacetic acid.

49. In its mass email Creative Compounds falsely stated and/or misleadingly stated that its customers must, "Beware of other diiodiothyroacetic [sic] acid products on the market that are not pure!" In warning customers to "beware" of other products on the market that "are not pure," Creative Compounds materially mislead consumers.

50. In its mass email Creative Compounds also falsely stated that diiodothyroacetic acid sold in the dietary supplement market is "highly diluted."

51. As the owner of the '533 Patent, ThermoLife manufactures, markets and sells all diiodothyroacetic acid legally used in dietary supplements. Accordingly, Creative Compounds' statements concerning diiodothyroacetic acid that is "not pure" and "highly diluted" are understood by consumers in the industry to refer directly diiodothyroacetic acid sold and manufactured by ThermoLife. These statements are literally false. At a minimum, Creative Compounds statements improperly mislead and/or deceive consumers.

52. In its mass email, Creative Compounds also falsely stated that its DIACtive brand of diiodothyroacetic acid is the "most pure, highest quality DIAC in the industry."

53. The diiodothyroacetic acid that ThermoLife markets and sells is pure and of the highest quality. Accordingly, Creative Compounds' statements that its product is the

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6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

"most pure" and the "highest quality" are literally false. At a minimum, Creative Compounds statements improperly mislead and/or deceive consumers.

54. Any dietary supplement that contained diiodothyroacetic acid that Creative Compounds sold or compounded for another supplement company to sell would compete directly with ThermoLife's Dicana.

55. Creative Compounds' actions as set forth above were intentional and outrageous. Punitive damages should therefore be awarded in an amount sufficient to punish Creative Compounds and to deter Creative Compounds and others similarly situated from engaging in similar conduct in the future.

**COUNT I — PATENT INFRINGEMENT**

56. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraph of this Complaint, as if fully set forth herein.

57. This cause of action arises under the Laws of the United States, Title 35, United States Code, in particular under 35 U.S.C. § 271(a).

58. The '533 Patent is a valid and enforceable patent.

59. Creative Compounds, acting through and by its respective officers and owners, has, without authority, consent, right or license, and in direct infringement of the '533 Patent, imported, made, used, and/or sold Infringing Products in this country, and such Infringing Products have been marketed in this jurisdiction and district.

60. Defendant's infringing conduct is willful, intentional and unlawful and, upon information and belief, will continue unless enjoined by this Court.

61. Plaintiffs have no adequate remedy at law for the harm caused by Creative Compounds' acts.

62. By reason of Defendant's acts complained of herein, Plaintiffs have suffered monetary damages in an amount that has not yet been determined, but upon information

Kercsmar & Feltus PLLC
6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

and belief, is substantially in excess of the sum or value of $75,000, exclusive of interest and costs.

63. Due to the intentional nature of Defendant's acts, this is an exceptional case in which Plaintiffs are entitled to treble damages, attorneys' fees and costs pursuant to 35 U.S.C. §§ 284 and 285.

64. Pursuant to 35 U.S.C. § 284, Plaintiffs are entitled to: an accounting by Defendant of funds comprising all revenues received through the commercial exploitation of Infringing Products; the imposition of a constructive trust for the benefit of Plaintiffs for all such funds in the custody or control of Defendant; and to such other damages to which Plaintiffs may be determined to be entitled.

**COUNT II — INDUCEMENT OF PATENT INFRINGEMENT**

65. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraph of this Complaint, as if fully set forth herein.

66. This cause of action arises under the Patent Laws of the United States, Title 35, United States Code, in particular under 35 U.S.C. § 271(b).

67. The '533 Patent is a valid and enforceable patent.

68. Upon information and belief, defendant, acting through and by its respective officers and owners, have, in this country, actively and/or intentionally induced others to use and/or sell Infringing Products, in direct infringement of the '533 Patent.

69. Defendant's infringing conduct is willful, intentional and unlawful and, upon information and belief, will continue unless enjoined by this Court.

70. Plaintiffs have no adequate remedy at law for the harm caused by Defendant's acts.

71. By reason of Defendant's acts complained of herein, Plaintiffs have suffered monetary damages in an amount that has not yet been determined, but upon information

Kercsmar & Feltus PLLC
6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

and belief, is substantially in excess of the sum or value of $75,000, exclusive of interest and costs.

72. Due to the intentional nature of Defendant's acts, this is an exceptional case in which Plaintiffs are entitled to treble damages, attorneys' fees and costs pursuant to 35 U.S.C. §§ 284 and 285.

73. Pursuant to 35 U.S.C. § 284, Plaintiffs are entitled to: an accounting by Defendant of funds comprising all revenues received through the commercial exploitation of Infringing Products; the imposition of a constructive trust for the benefit of Plaintiffs for all such funds in the custody or control of Defendant; and to such other damages to which Plaintiffs may be determined to be entitled.

**COUNT III — CONTRIBUTORY PATENT INFRINGEMENT**

74. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraph of this Complaint, as if fully set forth herein.

75. This cause of action arises under the Patent Laws of the United States, Title 35, United States Code, in particular under 35 U.S.C. § 271(c).

76. The '533 is a valid and enforceable patent.

77. Defendant is liable for contributory infringement, pursuant to 35 U.S.C. § 271(c), in that Defendant have imported, made, and/or sold within the United States a component of a patented combination or composition, consisting of a material part of the invention, knowing the same to be especially made or adapted for use in the infringement of the '533 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

78. Defendant's infringing conduct is willful, intentional and unlawful and, upon information and belief, will continue unless enjoined by this Court.

79. Plaintiffs have no adequate remedy at law for the harm caused by Defendant's acts.

Kercsmar & Feltus PLLC
6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

80. By reason of Defendant's acts complained of herein, Plaintiffs have suffered monetary damages in an amount that has not yet been determined, but upon information and belief, is substantially in excess of the sum or value of $75,000, exclusive of interest and costs.

81. Due to the intentional nature of Defendant's acts, this is an exceptional case in which Plaintiffs are entitled to treble damages, attorneys' fees and costs pursuant to 35 U.S.C. §§ 284 and 285.

82. Pursuant to 35 U.S.C. § 284, Plaintiffs are entitled to: an accounting by Defendant of funds comprising all revenues received through the commercial exploitation of Infringing Products; the imposition of a constructive trust for the benefit of Plaintiffs for all such funds in the custody or control of Defendant; and to such other damages to which Plaintiffs may be determined to be entitled.

**COUNT IV — FALSE ADVERTISING UNDER 15 U.S.C. § 1125(a)(1)(B)**

83. ThermoLife repeats and realleges each and every allegation contained in the foregoing paragraph of this Complaint, as if fully set forth herein.

84. As alleged above, Creative Compounds has made false statements of fact in a commercial advertisement about its products.

85. To the extent any statements made by Creative Compounds and alleged herein is not literally false, Creative Compounds has made statements that improperly mislead and/or deceive consumers.

86. Creative Compounds' statements actually deceive or have the tendency to deceive a substantial segment of its audience.

87. Creative Compounds' deception is material, in that it is likely to influence the purchasing decision.

88. Creative Compounds has caused the false statements alleged above to enter interstate commerce.

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6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

89. ThermoLife has been injured as a result of Creative Compounds' false statements, either by direct diversion of sales from itself to Defendant or by a lessening of the goodwill associated with ThermoLife's products.

90. ThermoLife has suffered a commercial injury based upon a misrepresentation about Creative Compounds' products.

91. ThermoLife's injury is competitive, i.e., harmful to the ThermoLife's ability to compete with Creative Compounds.

92. Creative Compounds' false statements cause irreparable harm to ThermoLife and ThermoLife's goodwill and business opportunities.

93. Creative Compounds' false statements are still available on the internet and barring an order from this Court those statements will not be removed from the internet, injunctive permanent relief is necessary to prevent further irreparable harm to ThermoLife's business and goodwill. To prevent further immediate and irreparable harm to ThermoLife a permanent injunction should enter requiring Creative Compounds and those acting in concert with it to remove from the internet any false information Creative Compounds has published.

94. Creative Compounds' conduct as alleged is willful and exceptional, such that ThermoLife is entitled to an award of treble damages and its attorneys' fees under 15 U.S.C. § 1117.

## JURY TRIAL DEMAND

1. Plaintiffs request a trial by jury on all aspects of the Complaint.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment against Defendant Creative Compounds as follows:

A. For a judicial determination and declaration that the '533 Patent is valid and enforceable;

B. That a preliminary and permanent injunction issue against Defendant, its agents, officers, directors, employees, attorneys, successors and assigns, all parent and subsidiary entities, and all those acting for or on the behalf of Defendant, or in active concert, participation, or combination with it, including customers and distributors, prohibiting Defendant from:

i. continuing acts of infringement of the '533 Patent;

ii. making, using, selling and/or importing Infringing Products, to include any colorable imitation thereof;

C. That an Order issue from this Court requiring Defendant, its officers, agents, servants and employees, to deliver up to this Court for destruction all articles and materials infringing upon the rights of Plaintiffs and all formulations and other matter or materials for reproducing such Infringing Products;

D. That Defendant be required to file with the Court within thirty (30) days after entry of an injunctive order or final judgment a written statement under oath setting forth the manner in which Defendant has complied with the order or final judgment;

E. Awarding Plaintiffs damages sustained due to Defendant's infringement of the '533 Patent;

F. In the alternative, ordering Defendant to pay Plaintiffs all profits, gains, and advantages Defendant has received or obtained from its unlawful conduct, in an amount to be determined at trial;

G. In the alternative, that a reasonable royalty for Defendant's infringement be awarded to Plaintiffs pursuant to 35 U.S.C. § 284;

H. That, due to Defendant's willful infringement of Plaintiff's patent rights, Defendant be ordered to pay Plaintiffs treble damages pursuant to 35 U.S.C. §284;

I. An award of the costs of this action, including pre- and post-judgment interest, pursuant to 35 U.S.C. § 284;

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6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

J. That, due to Defendant's willful and flagrant disregard of Plaintiffs' patent rights, Defendant be ordered to pay Plaintiffs their reasonable attorneys' fees and experts' fees pursuant to 35 U.S.C. § 285;

K. For an award of treble damages under 15 U.S.C. § 1117 and 15 U.S.C. § 1125(a).

L. For an award of attorneys' fees under 15 U.S.C. § 1117.

M. For punitive damages in an amount sufficient to deter Creative Compounds from future wrongful and outrageous conduct;

N. An Order permanently enjoining, Defendant and all those persons in active concert or participation with them, from making false statements on the internet their products and an order requiring Defendant and those acting in concert or participation with them to remove the false statements from the internet regarding Defendant's products; and

O. For such other and further relief as this Court deems necessary, just and proper under the circumstances.

DATED this 7th day of October, 2011.

KERCSMAR & FELTUS PLLC

By *s/ Gregory B. Collins*

Gregory B. Collins
Jenessa G. B. Coccaro
6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
*Attorneys for Plaintiffs*

Kercsmar & Feltus PLLC
6263 North Scottsdale Road, Suite 320
Scottsdale, Arizona 85250
(480) 421-1001

# EXHIBIT A



US007919533B2

(12) **United States Patent**
**Abraham et al.**

(10) **Patent No.: US 7,919,533 B2**
(45) **Date of Patent: Apr. 5, 2011**

(54) **DIIODOTHYROACETIC ACID AND METHOD OF USE**

(76) Inventors: **Sal Abraham**, Watchung, NJ (US); **Ron Kramer**, Phoenix, AZ (US)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1020 days.

(21) Appl. No.: **10/904,029**

(22) Filed: **Oct. 20, 2004**

(65) **Prior Publication Data**

US 2006/0083779 A1 Apr. 20, 2006

(51) **Int. Cl.**
*A61K 31/195* (2006.01)

(52) **U.S. Cl.** ..... **514/909**; 514/567

(58) **Field of Classification Search** ..... 424/434
See application file for complete search history.

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*Primary Examiner* — Anand U Desai
*Assistant Examiner* — Melissa S Mercier
(74) *Attorney, Agent, or Firm* — Booth Udall, PLC

(57) **ABSTRACT**

The present invention relates to a method of administering an effective amount of a diiodothyroacetic acid in order to shift the proportion between lean body mass and adipose tissue in favor of lean body mass in human individuals.

**15 Claims, No Drawings**

# DIIODOTHYROACETIC ACID AND METHOD OF USE

## BACKGROUND OF INVENTION

Over recent years obesity has reached epidemic proportions. Obesity contributes to more than 300,000 deaths each year and according to federal guidelines, half the population is overweight and a third is obese. Obesity is defined as an excess proportion of total body fat correlating with a body weight greater than 20 percent of ideal body weight (IBW). Body Mass Index (BMI) is another method to determine whether or not an individual is obese. BMI utilizes a mathematical equation consisting of weight and height measurements in order to determine total body fat. A BMI between 25-29.9 indicates an individual is overweight. Causes for obesity include genetic, environmental, economic, emotional, and physiological factors. These factors can then lead to the over consumption of total calories. The amount of total calories consumed versus the amount of total calories burned determines the amount of fat stored for energy reserves. Calories or Kcals (kilocalories) are defined as the amount of heat necessary to raise the temperature of 1 gram of water 1 degree Celsius. The amount of total calories burned is defined as the calories utilized by exercise plus basal metabolic rate (BMR) or resting metabolic rate (RMR). BMR represents the amount of calories needed to maintain IBW at rest. Increasing BMR results in fewer calories stored as fat and can promote weight loss if the amount calories burned is greater than the amount of calories ingested. One of the main factors that controls BMR is the percentage of lean body weight.

Standard medical therapy for obesity includes oral prescription medications. Most of these medications are designed to regulate appetite by releasing serotonin or catecholamine. For instance Sanorex, Mazanor, Adipex-P, and Meridia are common appetite suppressant medications. However most of these medications can only be used on a short term basis and are scheduled as controlled substances due to the fact that they can become addictive. Other side effects include increased heart rate, blood pressure, constipation and insomnia. Merida is the only appetite suppressant that has been approved for long term use. Another long term pharmaceutical approach to weight loss is the fat absorption inhibitor Xenical. Xenical works by blocking about 30 percent of dietary fat from being absorbed. Enzymes in the digestive system, called lipases, assist in the digestion of dietary fats. Xenical attaches to the lipases and inhibits the digestion of dietary fat as triglycerides into absorbable free fatty acids and monoglycerides, which are then excreted in the bowel. Xenical literature recommends not ingesting more than 30 percent of total calories from dietary fat per day due to concerns regarding loose bowels. It appears that a common and unpleasant side effect of Xenical includes flatulence and loose bowels when a high fat diet is consumed during Xenical treatment.

The previously mentioned weight control methods do not take into account the importance of maintaining or increasing the lean body mass in the process of weight loss. Medical methods to decrease body fat often contribute to the catabolic wasting of lean body mass. Increased lean body mass enhances metabolism and helps in losing fat weight, as well as maintaining the accomplished weight reduction. Diminished lean body mass decreases metabolism and results in difficulties in maintaining healthy body weight. An ideal weight management approach should be to reduce body weight to acceptable levels by restoring the optimal proportions of fat to lean body mass. By maintaining or increasing the lean body mass while simultaneously reducing body fat, the weight loss regimen would serve the general purpose of improving the overall health of the individual.



The present invention relates to a method of administering an effective amount of an iodothyroacetic acid analog in order to shift the proportion between lean body mass and adipose tissue in favor of lean body mass in a human individual. Iodothyronines traditionally have been utilized to treat thyroid disorders such as hypo and hyper thyroidism. The most common iodothyronines consist of tetraiodothyronine (T4), triiodothyronine (T3), diiodothyronine (T2), and monoiodothyronine (T1) but also include the acetic acid analogs Tetraiodothyroacetic Acid (TETRAC or TA4) and Triiodothyroacetic Acid (TRIAC or TA3). We purpose for the first time that the use of diiodothyroacetic acid (TA2) is novel and unobvious due to its ability to shift the proportion between lean body mass and adipose tissue in favor of lean body mass without causing sympathomimetic stimulation, loose bowel or addictive symptomology commonly associated with obesity related prescription and over the counter medications. This unobvious function can also increase the variables associated with physical performance for the regulation of athletic function in humans.

The thyroid gland, in response to stimulation by TSH, produces 3,5,3',5'-tetratiodothyronine (T4), T3, and reverseT3. The synthesis of these hormones requires the amino acid tyrosine and the trace mineral iodine. Within the cells of the thyroid gland, iodide is oxidized to iodine by hydrogen peroxide, a reaction termed the organification of iodide. Iodine then binds to the number 3 position in the tyrosyl ring in a reaction catalyzed by the thyroid peroxidase enzyme, a reaction yielding 3-monoiodotyrosine (MIT). A subsequent addition of another iodine to the number 5 position of the tyrosyl residue on MIT creates 3,5-diiodotyrosine (DIT). T4 is created by the condensation or coupling of two DIT molecules. Within the thyroid, smaller amounts of DIT can also condense with MIT to form either T3 or reverseT3.

Iodothyronines have been patented for a number of applications. For instance, U.S. Pat. No. 4,673,691 by Bachynsky demonstrates a method for inducing human weight loss. U.S. Pat. No. 5,910,569 by Latham et al. describes a method for the use of iodothyronine polymers for the treatment of thyroid disorders. U.S. Pat. No. 6,380,255 by Lavin et al. describes a method for the treatment of dermal skin atrophy using thyroid hormone compounds.

The iodothyroacetic acid analogs utilized in this invention consist of all isomers, esters, salts, ethers, metabolites and analogs of diiodothyroacetic acid. This naturally occurring acetic acid analog is a direct metabolite of triiodothyronine (T3) and triiodothyroacetic acid (Triac) as demonstrated in Endocrinology October 1990; 127(4): 1617-24 and Endocrinology July 1989; 125(1): 424-32. It should be understood that this invention is not construed as limited in scope by the details contained therein, as it is apparent to those skilled in the art that modification in materials and methods can be made without deviating from the scope of the invention.

U.S. Pat. No. 4,673,691 by Bachynsky describes a method for human weight reduction with 2,4-dinitrophenol and a thyroid hormone. The dinitrophenol is administered to elevate body temperature, while the thyroid preparation is utilized maintain T3 levels that were present at the onset of the treatment. This invention represents an improvement in standard weight loss preparations due to the combination of dinitrophenol and T3. This combination represents an improvement in the use of dinitrophenol for weight loss although dinitrophenol is toxic and may lead to adverse reactions. U.S. Pat. No. 4,673,691 by Bachynsky addresses weight loss while

the present invention focuses on shifting the proportion between lean body mass and adipose tissue in favor of lean body mass. This combination represents an improvement in the use of dinitrophenol for weight loss although dinitrophenol is toxic and may lead to adverse reactions.

U.S. Pat. No. 5,910,569 by Latham et al. describes a method for the synthesis of various iodothyronine polymers for use in the treatment of thyroid disorders. Since these iodothyronine polymers are released by digestive proteolysis it is expected that they would have a long physiologic effect because of the sustained release from the polymers of the monomeric thyroid hormones and thus give stable, consistent pharmaceutical compositions for the treatment of thyroid hormone deficiencies. This combination represent an improvement in the use of iodothyronines for the treatment of thyroid hormone deficiencies although these polymers do not address the use of diiodothyroacetic acid to shift the proportion between lean body mass and adipose tissue in favor of lean body mass.

U.S. Pat. No. 6,380,550 by Lavin describes a method for treating dermal atrophy of the skin. Lavin has found that topical application of a composition comprising at least one thyroid hormone compound or thyroid hormone-like compound in a pharmacologically acceptable base is effective in treating dermal atrophy of the skin. It also provides an improved cosmetic appearance to aging, atrophied, steroid-affected, or sun damaged skin. This combination represents a novel and unobvious use of iodothyronines for the treatment of dermal atrophy of the skin although this invention does not address the use of diiodothyroacetic acid to shift the proportion between lean body mass and adipose tissue in favor of lean body mass.

## SUMMARY OF INVENTION

The present invention relates to a method of administering an effective amount of an iodothyroacetic acid in order to shift the proportion between lean body mass and adipose tissue in favor of lean body mass in a human individual. This unobvious function can also increase the variables associated with physical performance for the regulation of athletic function in humans. The method comprises administering to humans an effective amount of a composition consisting of an iodothyroacetic acid such as but not limited to all isomers, esters, salts, ethers, metabolites and analogs of 3,3' diiodothyroacetic acid and 3,5 diiodothyroacetic acid.

Diiodothyroacetic acid exerts a direct enhancement of metabolic rate via an increase in oxygen consumption and body temperature. This increase in metabolic rate results in an enhancement of the utilization of orally consumed nutrients. 3,3' diiodothyroacetic acid is a precursor to T3, Triac, and T2. Small increases in T3 result in increased protein synthesis for muscle tissue accretion. Thus the said compound can be given to humans either in conjunction with or without a high protein diet (1.25 to 1.8 grams protein/kilogram of body weight) and proper anaerobic training program in order to shift the proportion between lean body mass and adipose tissue in favor of lean body mass for the regulation body weight.

## DETAILED DESCRIPTION

The chemical term iodothyroacetic acid may refer to but is not limited to 3,3' diiodothyroacetic acid and 3,5 diiodothyroacetic acid. Possible alternatives include all isomers, esters, salts, ethers, metabolites and analogs of diiodothyroacetic acid. This invention concerns a diiodothyroacetic acid and all previously mentioned alternatives. The previous examples of various diiodothyroacetic acids are presented by way of illustration only. It should be understood that this invention is not construed as limited in scope by the details contained therein, as it is apparent to those skilled in the art that modifications in materials and methods can be made without deviating from the scope of the invention.

The iodoamino acids TA4 and TA3 are products of deamination and oxidative decarboxylation of T4 and T3 and have been detected in serum by direct RIA measurements. Reported mean concentrations in the serum of healthy adults have been 8.7 nanograms per deciliter and 2.6 nanograms per deciliter for TA3 and 28 nanograms per deciliter for TA4. Serum TA4 levels are reduced during fasting and in patients with severe illness, although the percentage of conversion of T4 to TA4 is increased. The concentration of serum TA3 remains unchanged during the administration of replacement doses of T4 and T3. It has been suggested that intracellular rerouting of T3 to TA3 during fasting is responsible for the maintenance of normal serum TSH levels in the presence of low T3 concentrations.

The sulfate conjugate 3,3'-diiodothyroacetic acid (3,3'-TA2S) was discovered in plasma, and occasionally in bile, of 6-propyl-2-thiouracil-treated rats after administration of T3 as shown in Endocrinology October 1990; 127(4): 1617-24. The significant plasma 3,3'-TA2S levels, even in unanesthetized animals, illustrate the physiological relevance of this T3 metabolite. Diiodothyroacetic acid is a direct naturally occurring metabolite of T3, Triac, and T2, which has never been investigated or sold as a new drug therefore it may be sold as a dietary supplement.

The biosynthetic pathway of diiodothyroacetic acid is unique in that it possesses several direct pathways to different thyroid hormones in contrast to other acetic acid analogs such as T3A and T4A. Diiodothyroacetic acid has direct reversible pathways to T3, Triac and T2. The ability to increase the levels of these different thyroid hormones is one aspect of diiodothyroacetic acid uniqueness. The other aspect is its ability to shift the proportion between lean body mass and adipose tissue in favor of lean body mass via small increases in T3 for enhanced protein synthesis and muscle tissue accretion.

Without being bound to any theory, effective administration of diiodothyroacetic acid shifts the proportion between lean body mass and adipose tissue in favor of lean body mass due to its location in the thyroid biosynthetic pathway. Diiodothyroacetic acid exerts a direct enhancement of metabolic rate via an increase in oxygen consumption and body temperature. This increase in metabolic rate results in an enhancement of the utilization of orally consumed nutrients. Diiodothyroacetic acid acts as a precursor hormone resulting in specific small increases in T3, Triac, and T2. Small increases in T3 facilitate protein synthesis for muscle anabolism. In the present method of promoting lean body mass, diiodothyroacetic acid should be administered in a daily dose of from about 1 mcg to about 6 mg. It is preferred that the daily dose be divided into a plurality of individual doses. It is further preferred that three to six individual doses be used. In any case, the individual doses are preferably from about 100 mcg to about 1 mg each. After every 4 weeks of continual use, a 2-week cessation period is recommended. Thus the said compound can be given to humans either in conjunction with or without a high protein diet (1.25 to 1.8 grams protein per kilogram of body weight) and proper anaerobic training program in order to shift the proportion between lean body mass and adipose tissue in favor of lean body mass for the purpose of body weight regulation.

After an extensive review of the scientific literature and previous patents regarding the ability of diiodothyroacetic acid to alter body composition, it then became the focus of this invention that all isomers, esters, salts, ethers, metabolites and analogs of diiodothyroacetic acid could be administrated perorally as an effective means to shift the proportion between lean body mass and adipose tissue in favor of lean body mass in humans. The oral daily doses can be between 1 mcg to 6 mg per day. The preferred daily dosing schedule should be divided into 3-6 sub dose applications per day in order maintain adequate blood hormone concentrations. In addition to peroral use, several other routes including transdermal, sublingual, intranasal, and parenteral administration may be effectively utilized.

What is claimed is:

**1**. A method of promoting lean body mass in a human individual having a body mass index of at least 25, comprising directly administering to the individual an effective amount of diiodothyroacetic acid.

**2**. The method of claim **1**, wherein the diiodothyroacetic acid comprises one of 3,3' diiodothyroacetic acid and 3,5 diiodothyroacetic acid.

**3**. The method of claim **1**, wherein the diiodothyroacetic acid is selected from the group consisting of diiodothyroacetic acid isomers, esters, salts, and ethers thereof.

**4**. The method of claim **1**, wherein administration is selected from the group comprising peroral, transdermal, sublingual, intranasal, and parenteral administration.

**5**. The method of claim **1**, wherein the diiodothyroacetic acid is administered in a daily dose in a range of about 1 microgram to about 6 milligrams.

**6**. A method of increasing a proportion of lean body mass to adipose tissue in a human individual having a body mass index of at least 25, comprising directly administering to the individual an effective amount of diiodothyroacetic acid.

**7**. The method of claim **6**, wherein the diiodothyroacetic acid comprises one of 3,3' diiodothyroacetic acid and 3,5 diiodothyroacetic acid.

**8**. The method of claim **6**, wherein the diiodothyroacetic acid is selected from the group consisting of diiodothyroacetic acid isomers, esters, salts, and ethers thereof.

**9**. The method of claim **6**, wherein administration may be selected from the group comprising peroral, transdermal, sublingual, intranasal, and parenteral administration.

**10**. The method of claim **6**, wherein the diiodothyroacetic acid is administered in a daily dose in a range of about 1 microgram to about 6 milligrams.

**11**. A dietary supplement comprising diiodothyroacetic acid.

**12**. The composition of claim **11**, wherein the diiodothyroacetic acid comprises one of 3,3' diiodothyroacetic acid and 3,5 diiodothyroacetic acid.

**13**. The composition of claim **11**, wherein the diiodothyroacetic acid is selected from the group consisting of diiodothyroacetic acid isomers, esters, salts, and ethers thereof.

**14**. The composition of claim **11**, wherein administration is selected from the group comprising peroral, transdermal, sublingual, intranasal, and parenteral administration.

**15**. The composition of claim **11**, wherein the diiodothyroacetic acid is administered in a daily dose in a range of about 1 microgram to about 6 milligrams.

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# EXHIBIT B

**From:** Customer Service [mailto:customerservice@creativecompounds.com]
**Sent:** Thursday, September 22, 2011 3:29 PM
**To:** purchasing@thermolife.com; ron@thermolife.com
**Subject:** DIACtive diiodothyroacetic acid (DIAC)

Creative Compounds is pleased to introduce ***DIACtive*** brand of diiodothyroacetic acid (DIAC), one of the most exciting dietary supplements of the decade. Having worked extensively with this novel ingredient, Creative Compounds knows all of the intricacies surrounding its pharmacology and usage. We have the unique ability to help your company properly formulate and integrate this ingredient into a top selling product on the market. Beware of other diiodiothyroacetic acid products on the market that are not pure! Beware of other products on the market that are highly diluted but sell for an extremely high price. DIACtive is the most pure, highest quality DIAC in the industry and is GUARANTEED to be the lowest price diiodothyroacetic acid in the industry.

Please see attached product summary and contact Creative Compounds today for more info.

# EXHIBIT C

creative compounds

Presents

# DIACtive

## Dietary Supplements

## Creative Compounds

is pleased to introduce DIACtive brand of diiodothyroacetic acid (DIAC), one of the most exciting dietary supplements of the decade. Having worked extensively with this novel ingredient, Creative Compounds knows all of the intricacies surrounding its pharmacology and usage. We have the unique ability to help your company properly formulate and integrate this ingredient into a top selling product on the market.

Beware of other diiodothyroacetic acid products on the market that are not pure! Beware of other products on the market that are highly diluted but sell for an extremely high price. DIACtive is the most pure, highest quality DIAC in the industry and is GUARANTEED to be the lowest price diiodothyroacetic acid in the industry.

*What does DIACtive do?*

*1. Powerfully increases metabolism*

*2. Noticeably initiates the shedding of large quantities of adipose tissue*

*3. Protects precious muscle tissue from being destroyed while losing weight*

*4. Anabolic! Helps build muscle with a calorie surplus*

*5. Reduces cholesterol and triglyceride levels*

*6. No jittery feelings...no side effects*

**Remember! Stop paying too much for overpriced, low quality DIAC. Contact Creative Compounds and get the best quality at the lowest price!**