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11 NATURAL ALTERNATIVES  
12 INTERNATIONAL, INC.

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**UNITED STATES DISTRICT COURT**  
**SOUTHERN DISTRICT OF CALIFORNIA**

NATURAL ALTERNATIVES  
INTERNATIONAL, INC.,

Plaintiff,

v.

HI-TECH PHARMACEUTICALS, INC.  
doing business as ALR Industries, APS  
Nutrition, Innovative Laboratories,  
Formutech Nutrition, LG Sciences and  
Sports 1, and DOES 1-100,

Defendant.

Case No. 3:16-cv-02343-DMS-BGS

**FIRST AMENDED COMPLAINT  
FOR BREACH OF CONTRACT,  
PATENT INFRINGEMENT AND  
TRADEMARK INFRINGEMENT**

**DEMAND FOR JURY TRIAL**

Plaintiff, Natural Alternatives International, Inc. (“NAI”), hereby brings this First Amended Complaint against Defendant, Hi-Tech Pharmaceuticals, Inc. (doing business as ALR Industries, APS Nutrition, Innovative Laboratories, Formutech Nutrition, LG Sciences and Sports 1) (“Hi-Tech”), and alleges as follows:

**INTRODUCTION**

1. NAI sells its branded CarnoSyn® beta-alanine, an amino acid, to customers throughout the United States and in other countries. NAI’s product is covered by a robust portfolio of patent and trademark rights. Hi-Tech entered into a

1 CarnoSyn® patent and trademark license agreement with NAI in July 2015. That  
2 agreement provides NAI with the right to periodically audit Hi-Tech. NAI invoked its  
3 audit rights on August 30, 2016, however, in breach of its contractual obligations, Hi-  
4 Tech ignored NAI's audit demand. The July 2015 patent and trademark license does  
5 not release Hi-Tech from past infringement. Further, NAI files this action to stop Hi-  
6 Tech from intentionally and willfully infringing upon NAI's patent and trademark  
7 rights and wrongfully interfering with NAI's CarnoSyn® beta-alanine business.

### 8 **PARTIES**

9 2. NAI is a Delaware corporation with its principal place of business in San  
10 Marcos, California.

11 3. Hi-Tech is a Georgia corporation with its principal place of business  
12 located at 6015-B Unity Drive, Norcross, Georgia. It also does business as ALR  
13 Industries, APS Nutrition, Innovative Laboratories, Formutech Nutrition, LG Sciences  
14 and Sports 1.

15 4. The true names and capacities, whether individual, corporate, associate or  
16 otherwise of defendants sued herein as DOES 1-100, inclusive, are unknown to NAI  
17 at the present time and NAI therefore sues such defendants by fictitious names. NAI  
18 will amend this complaint, by leave of Court if necessary, to show such true names  
19 and capacities when the same have been ascertained. Such defendants will be brands  
20 that do not buy beta-alanine from NAI and/or comingle beta-alanine and then use it to  
21 manufacture dietary supplements, offer to sell or sell the finished products to end  
22 users, and/or the end users, including Hi-Tech's customers who have purchased the  
23 accused products and those who have been induced to infringe the patents-in-suit.

### 24 **JURISDICTION AND VENUE**

25 5. The Court has subject matter jurisdiction over the underlying action  
26 pursuant to 28 U.S.C. §§ 1331 and 1338 and 15 U.S.C. § 1121(a).



1 the patents assigned to NAI, Dr. Roger Harris, has been recognized for his work in  
2 nutritional supplements, particularly his work in several studies using CarnoSyn®  
3 beta-alanine. He has a lifetime achieve award from the International Society of Sports  
4 Nutrition.

5 10. NAI is the owner of U.S. Patent No. 5,965,596 (“the ‘596 patent”), issued  
6 on or about October 12, 1999, entitled “Methods and compositions for increasing the  
7 anaerobic working in tissues.” A copy of the ‘596 patent is attached as Ex. 1 and  
8 incorporated by reference.

9 11. NAI is the owner of U.S. Patent No. 7,825,084 (“the ‘084 patent”), issued  
10 on or about November 2, 2010, entitled “Methods and compositions for increasing the  
11 anaerobic working capacity in tissues.” A copy of the ‘084 patent is attached as Ex. 2  
12 and incorporated by reference.

13 12. NAI is the owner of U.S. Patent No. RE45,947 (“the ‘947 patent”),  
14 issued on or about March 29, 2016, entitled “Methods and compositions for increasing  
15 the anaerobic working capacity in tissues.” A copy of the ‘947 patent is attached as  
16 Ex. 3 and incorporated by reference.

17 13. NAI is the owner of U.S. Patent No. 8,993,610 (“the ‘610 patent”), issued  
18 on or about March 31, 2015, entitled “Methods and compositions for increasing the  
19 anaerobic working capacity in tissues.” A copy of the ‘610 patent is attached as Ex. 4  
20 and incorporated by reference.

21 14. NAI is the owner of U.S. Patent No. 8,470,865 (“the ‘865 patent”), issued  
22 on or about June 25, 2013, entitled “Methods and compositions for increasing the  
23 anaerobic working capacity in tissues.” A copy of the ‘610 patent is attached as Ex. 18  
24 and incorporated by reference.

25 15. By statute, the patents-in-suit are presumed valid, 35 U.S.C. § 282. None  
26 of them have been found invalid by a court.

16. Claim 1 of the '596 patent is directed to a method of regulating the hydronium ion concentration in human tissue by providing an amount of beta-alanine to the blood or blood plasma effective to increase beta-alanylhistidine dipeptide (carnosine) synthesis in the human tissue, exposing the human tissue to the blood or blood plasma and thereby increasing the carnosine in the human tissue.

17. Claim 3 of the '596 patent is directed to the method of claim 1, further comprising increasing a concentration of creatine in the human tissue.

18. Claim 5 of the '596 patent is directed to the method of claim 3, wherein increasing the amount of creatine in the human tissue includes providing an amount of creatine to the blood or blood plasma effective to increase the concentration of creatine in the human tissue.

19. Claim 1 of the '084 patent is directed to a human dietary supplement comprising beta-alanine in a unit dosage of between 0.4 grams to 16 grams.

20. Claim 2 of the '084 patent is directed to the human dietary supplement of claim 1, further comprising a creatine in a unit dosage of between about 0.4 grams to 16 grams.

21. Claim 3 of the '084 patent is directed to the human dietary supplement of claim 1, further comprising an L-histidine in a unit dosage of between about 0.08 grams to 8 grams.

22. Claim 34 of the '947 patent is directed to a human dietary supplement for increasing human muscle tissue strength comprising a mixture of creatine, a carbohydrate and free amino acid beta-alanine that is not part of a dipeptide, polypeptide or an oligopeptide, wherein the human dietary supplement does not contain a free amino acid L-histidine, wherein the free amino acid beta-alanine is in an amount that is from 0.4 g to 16.0 g per daily dose, wherein the amount increases the muscle tissue strength in the human, and wherein the human dietary supplement is formulated for one or more doses per day for at least 14 days.



1           29. Claim 5 of the '865 patent is directed to the method of claim 3, wherein  
2 increasing the amount of creatine in the tissue includes providing an amount of  
3 creatine to the blood or blood plasma effective to increase the concentration of  
4 creatine in the tissue.

5           30. NAI sells beta-alanine to customers in the United States engaged in  
6 interstate and foreign commerce. Its beta-alanine is branded and sold under the  
7 trademark CarnoSyn®. NAI also owns the entire right, title and interest to multiple  
8 trademarks, including the CarnoSyn® trademark, Serial No. 78372235 and  
9 Registration No. 3146289, and the Carnosyn Beta Alanine® trademark, Serial No.  
10 85606462 and Registration No. 4271217.

11           31. NAI has invested and continues to expend substantial funds to build,  
12 expand and promote sales of CarnoSyn® beta-alanine. NAI pursues legal avenues to  
13 protect its CarnoSyn® brand and intellectual property portfolio.

14           32. NAI maintains a website to promote and encourage sales of its branded  
15 beta-alanine at [www.carnosyn.com](http://www.carnosyn.com), the content of which is incorporated herein by  
16 reference.

17           33. When NAI sells CarnoSyn® beta-alanine to customers, the customers  
18 receive a scientifically-tested recognized product, a license to NAI's trademarks and  
19 patents, and are indemnified against product liability. The license extends only to the  
20 CarnoSyn® beta-alanine purchased from NAI, and does not extend to CarnoSyn®  
21 beta-alanine that contains or is mixed or comingled with any non-trademarked beta-  
22 alanine.

23 **B. HI-TECH**

24           34. Hi-Tech is a contract manufacturer that manufactures products for dietary  
25 supplement companies, including one or more products containing beta-alanine. In  
26 addition, Hi-Tech creates, manufactures, offers to sell and sells its own dietary  
27 supplement products to consumers across the United States, including California. Hi-  
28



1 Tech's products are available at retailers, including Amazon.com, GNC, Vitamin  
2 Shoppe and CVS.

3 35. Hi-Tech's owner and Chief Executive Officer is Jared Wheat ("Wheat").  
4 He has had prior run ins with the law involving drugs and dietary supplements. He  
5 and Hi-Tech are parties to an ongoing seizure action captioned *United States v.*  
6 *Undetermined Quantities of 1,3 Dimethylamylamine HCl (DMAA)*, No. 13-CV-3675  
7 (N.D. Ga.).

8 36. Hi-Tech maintains and operates a website at <https://hitechpharma.com>,  
9 the content of which is incorporated herein by reference.

10 37. Hi-Tech has manufactured, sold, and offered to sell dietary supplements  
11 under its own or one of its brand names containing beta-alanine to its customers in the  
12 United States in interstate commerce. In doing so, Hi-Tech has imported or purchased  
13 the raw material beta-alanine from others, and not NAI. Hi-Tech has not marked or  
14 virtually marked its products with NAI's applicable patent numbers.

15 38. In addition, to its own products, Hi-Tech acts as a contract manufacturer  
16 for other dietary supplement brand companies. Hi-Tech manufactures and sells dietary  
17 supplements containing beta-alanine in the United States in interstate commerce. In  
18 doing so, Hi-Tech has imported or purchased the raw material beta-alanine, used in  
19 the accused products, from others, and not NAI. By way of example, Hi-Tech has  
20 manufactured dietary supplements containing beta-alanine for its customer, Muscle  
21 Elements, without using CarnoSyn® beta-alanine purchased from NAI.

22 39. Hi-Tech is required under laws and regulations, including the Public  
23 Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L.  
24 No. 107-188) and regulations promulgated thereunder by the Food and Drug  
25 Administration ("FDA"), to maintain records for up to two years in order to identify  
26 the immediate previous sources and the immediate subsequent recipients of dietary  
27 supplements, including all the ingredients of the dietary supplements, manufactured or  
28



distributed by Hi-Tech. Hi-Tech is also required to permit inspection and photocopying of records related to the manufacture, processing, packaging, transporting, distribution, receipt, holding or importation of dietary supplements within 24 hours of receiving a request from the FDA.

**C. 2015 CARNOSYN® BETA-ALANINE LICENSE AGREEMENT**

40. In July 2015, NAI and Hi-Tech entered into a CarnoSyn® Beta-Alanine License Agreement (“Agreement”). The Agreement was signed by Wheat, the authorized representative of Hi-Tech, on July 9, 2015 and the authorized representative of NAI on July 16, 2015. The Effective Date of the Agreement was July 16, 2015. A true and correct copy of the Agreement is attached as Ex. 5 and incorporated by reference.

41. Among other things, the Agreement granted Hi-Tech a license to patent and trademark rights for “Raw Material” – *i.e.*, the raw material known as beta-alanine – it purchased from NAI, provided that Hi-Tech complied with the terms and conditions. *See, e.g.*, Ex. 5 at ¶¶ 1, 3. The Agreement did not provide any release for Past trademark and/or patent infringement by Hi-Tech.

42. The Agreement imposed certain obligations on Hi-Tech, including without limitation the following:

- (a) **No Comingled Products.** The patent and trademark license granted by the Agreement does “not include Raw Material purchased from NAI that contains or is mixed or comingled with any beta-alanine obtained from any source other than NAI.” *Id.* at ¶ 3.
- (b) **Product Labeling Requirements.** Hi-Tech agreed to mark any licensed product with the applicable patent and trademark designations. *Id.* at ¶ 4.
- (c) **Records.** “Licensee shall maintain accurate and complete records of all of its purchases and sales of Raw Material and products containing Raw Material for the term of this Agreement and for at least two years

thereafter, including dates, quantities and identity of the seller(s) for Licensee's purchases and dates, quantities and identity of Licensees customers. NAI shall have a right to audit and inspect Licensee's books and records pertaining to beta-alanine purchases and sales, Raw Material and Licensed Products, not more than once each calendar year, at NAI's expense, by an independent auditor selected by NAI and accepted by Licensee, which acceptance shall not be unreasonably withheld. Licensee shall also maintain accurate and complete records sufficient to demonstrate compliance with the marking provisions set forth in Section 4 herein and that NAI's Trademark rights were used properly under this Agreement. For purposes of clarity and to avoid any misunderstanding, Licensee shall maintain records sufficient to determine which products contain beta-alanine, how much beta-alanine is included in each product, the identity of the source of the beta-alanine and all other information sufficient to confirm such information contained in this Section 10." *Id.* at ¶ 10.

- (d) **Ownership of Rights.** "Licensee acknowledges and agrees the Patent Rights and the Trademark Rights are and will remain the sole and exclusive property of NAI, and that NAI is the owner of all proprietary rights and intellectual property rights associated therewith including, without limitation, all trademarks, trade dress, trade names, logos, domain names and service marks, together with all translations, adaptations, derivations and combinations, including all associated goodwill, and all applications, registrations, reservations and renewals in connection therewith, whether or not registered for the Patent Rights or the Trademark Rights. Except as otherwise permitted herein, Licensee will not take any action inconsistent with NAI's ownership of and rights

1 under the Patent Rights and Trademark Rights. Licensee will not contest  
2 or aid others in contesting the validity, enforceability or NAI's ownership  
3 of and/or rights in the Patent Rights and Trademark Rights." *Id.* at ¶ 5.

4 43. The Agreement also contains a Delaware choice of law provision and  
5 requires the successful or prevailing party to recover its reasonable attorneys' fees in  
6 any proceeding brought to enforce the Agreement or for breach, default or other  
7 dispute concerning it. *Id.* at ¶ 11. Further, as the licensee, Hi-Tech "acknowledges and  
8 agrees that any actual or threatened breach of this Agreement by it will constitute  
9 immediate and irreparable harm to NAI for which monetary damages would be an  
10 inadequate remedy and that injunctive relief is an appropriate remedy for such  
11 breach." *Id.*

12 44. The Agreement did not release or provide a covenant not to sue Hi-Tech  
13 for any past infringement of NAI trademark. The Agreement also permits NAI to sue  
14 Hi-Tech for any future patent or trademark infringement for products that either do  
15 not include CarnoSyn® beta-alanine or contain some CarnoSyn® beta-alanine  
16 comingled with beta-alanine purchased from a supplier other than NAI. The  
17 Agreement does not require Hi-Tech to exclusively purchase CarnoSyn® beta-alanine  
18 from NAI. If it does not do so, however, it is liable to NAI for infringement.

19 45. Since the July 16, 2015 Effective Date of the Agreement, Hi-Tech has  
20 purchased only about 1,000 kilograms of licensed CarnoSyn® beta-alanine from NAI.

21 46. This is far less than Hi-Tech's historical purchases of beta-alanine.  
22 Publicly available import records indicate that Hi-Tech has imported at least 131,120  
23 kilograms of beta-alanine since 2011. Ex. 19.

24 47. The publicly available import records indicate that in 2011, Hi-Tech  
25 imported at least 64,120 kilograms of beta-alanine, in 2012, Hi-Tech imported at least  
26 46,840 kilograms of beta-alanine, and in 2015, Hi-Tech imported at least 20,160  
27 kilograms of beta-alanine. *Id.*

1           48. On May 23, 2015, less than two months before the effective date of the  
2 Agreement, Hi-Tech imported 20,160 kilograms of beta-alanine. *Id.* Under the terms  
3 of the Agreement, if any of this 20,160 kilograms of beta-alanine was mixed with the  
4 1,000 kilograms of licensed CarnoSyn® beta-alanine from NAI and used in dietary  
5 supplements, those dietary supplements would not be licensed under the Agreement  
6 and would therefore infringe NAI's patents.

7           49. On or about August 30, 2016, NAI, by counsel, sent a letter to Wheat,  
8 Hi-Tech's CEO, invoking NAI's audit rights pursuant to paragraph 10 of the  
9 Agreement. In pertinent part, the letter stated: "Pursuant to Section 10 of the License  
10 Agreement, this letter serves as NAI's written notice to Hi-Tech of its request to  
11 inspect records for the past two years maintained by Hi-Tech as required by the  
12 License Agreement." The letter went on to demand that Hi-Tech "make available for  
13 onsite inspection and the copying of records listed by September 6, 2016." It further  
14 set forth the form and nature of the records to be provided as part of the audit. A true  
15 and correct copy of the letter is attached as Ex. 6 and incorporated by reference.

16           50. The Agreement does not require NAI to provide a notice period for the  
17 audit.

18           51. Hi-Tech did not comply with NAI's audit demand in breach of paragraph  
19 10 of the Agreement. Hi-Tech did not respond to NAI's letter by the September 6  
20 deadline. In fact, it has simply ignored its contractual obligations.

21           52. Since the complaint in this case was filed on September 15, 2016, Hi-  
22 Tech has not expressed any willingness to conduct the audit.

23           53. Hi-Tech has not complied with paragraph 4 of the Agreement by not  
24 marking or virtually marking any products made using CarnoSyn® Beta-Alanine with  
25 applicable patent numbers or trademarks.

26           54. The Agreement remains in force as NAI has not terminated the  
27 Agreement, nor has NAI threatened to terminate the Agreement. The Agreement is not  
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1 void and the license for the 1,000 kilograms of beta-alanine purchased from NAI is in  
2 place, provided this amount was not comingled, or mixed with beta-alanine bought, or  
3 obtained, from another source.

4 55. The Agreement did not obligate to provide Hi-Tech with notice of breach  
5 and an opportunity to cure before it filed this case.

6 **D. ACTS OF PATENT INFRINGEMENT BY HI-TECH**

7 56. As alleged below, Hi-Tech has infringed one or more claims of NAI's  
8 patents-in-suit.

9 **1. Jack'D Up**

10 57. Hi-Tech promotes and sells Jack'D Up through the website  
11 <https://hitechpharma.com/collections/muscle-strength/products/jackd-up>, which is  
12 incorporated by reference.

13 58. Jack'D Up is a human dietary supplement that contains beta-alanine. Ex.  
14 7.

15 59. Jack'D Up contains creatine. *Id.*

16 60. Jack'D Up is not marked with NAI's patents or the CarnoSyn®  
17 trademark. *Id.*

18 61. Under the Agreement, Licensed Products, *i.e.*, those products containing  
19 only beta-alanine obtained from NAI, shall be marked with the CarnoSyn® trademark  
20 and NAI's patents. Ex. 5 at ¶ 4.

21 62. On information and belief, and as a reasonable opportunity for further  
22 investigation or discovery will show, Hi-Tech does not mark Jack'D Up with NAI's  
23 patents or the CarnoSyn® trademark because it contains beta-alanine obtained from  
24 another source.

25 63. Hi-Tech infringes claim 1 of the '084 patent because it sells, and offers  
26 for sale, Jack'D Up, which is a human dietary supplement that contains between 0.4  
27 and 16 g of beta-alanine, which is not exclusively obtained from NAI, per unit dosage.

64. Hi-Tech infringes claim 2 of the '084 patent because it sells, and offers for sale, Jack'D Up, which is a human dietary supplement that contains between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, and creatine per unit dosage.

## **2. NO Overload**

65. Hi-Tech promotes and sells NO Overload on the website <https://hitechpharma.com/collections/muscle-strength/products/n-o-overload>, which is incorporated by reference.

66. NO Overload is a human dietary supplement that contains beta-alanine. Ex. 8.

67. NO Overload contains creatine. *Id.*

68. NO Overload contains carbohydrate. *Id.*

69. NO Overload does not contain L-histidine. *Id.*

70. NO Overload is a human dietary supplement that is formulated for one or more doses per day for at least 14 days. *Id.*

71. NO Overload is not marked with NAI's patents or the CarnoSyn® trademark. *Id.*

72. Under the Agreement, Licensed Products, *i.e.*, those products containing only beta-alanine obtained from NAI, shall be marked with the CarnoSyn® trademark and NAI's patents. Ex. 5 at ¶ 4.

73. On information and belief, and as a reasonable opportunity for further investigation or discovery will show, Hi-Tech does not mark NO Overload with NAI's patents or the CarnoSyn® trademark because it contains beta-alanine obtained from another source.

74. Hi-Tech infringes claim 1 of the '084 patent because it sells, and offers for sale, NO Overload, which is a human dietary supplement that contains between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, per unit dosage.

1           75. Hi-Tech infringes claim 2 of the '084 patent because it sells, and offers  
2 for sale, NO Overload, which is a human dietary supplement that contains between 0.4  
3 and 16 g of beta-alanine, which is not exclusively obtained from NAI, and creatine per  
4 unit dosage.

5           76. Hi-Tech infringes claim 34 of the '947 patent because it sells, and offers  
6 for sale, NO Overload, which contains beta-alanine, which is not exclusively obtained  
7 from NAI, between 0.4 and 16 grams per daily dose, creatine and carbohydrate, does  
8 not contain L-histidine and is formulated for one or more doses per day for at least 14  
9 days.

### 10           **3. Phosphagen**

11           77. Hi-Tech promotes and sells a product, Phosphagen on the website  
12 <https://hitechpharma.com/collections/muscle-strength/products/phosphagen>, which is  
13 incorporated by reference.

14           78. Phosphagen is a human dietary supplement that contains beta-alanine.  
15 Ex. 9.

16           79. Phosphagen contains creatine. *Id.*

17           80. Phosphagen is not marked with NAI's patents or the CarnoSyn®  
18 trademark. *Id.*

19           81. Under the Agreement, Licensed Products, *i.e.*, those products containing  
20 only beta-alanine obtained from NAI, shall be marked with the CarnoSyn® trademark  
21 and NAI's patents. Ex. 5 at ¶ 4.

22           82. On information and belief, and as a reasonable opportunity for further  
23 investigation or discovery will show, Hi-Tech does not mark Phosphagen with NAI's  
24 patents or the CarnoSyn® trademark because it contains beta-alanine obtained from  
25 another source.

26           83. Hi-Tech infringes claim 1 of the '084 patent because it sells, and offers to  
27 sell, Phosphagen, which is a human dietary supplement that contains between 0.4 and  
28 16 g of beta-alanine, which is not exclusively obtained from NAI, per unit dosage.



84. Hi-Tech infringes claim 2 of the '084 patent because it sells, and offers to sell, Phosphagen, which is a human dietary supplement that contains between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, and creatine per unit dosage.

#### 4. APS Beta-Alanine

85. Hi-Tech, doing business as APS Nutrition (“APS”), sells and promotes products through its website, which is linked to the Hi-Tech Pharmaceuticals website. One of the products APS promotes and sells is APS Beta Alanine on the website <http://www.apsnutrition.com/collections/all-products/products/beta-alanine>, which is incorporated by reference.

86. APS Beta Alanine is a human dietary supplement that contains 2 g of beta-alanine per dosage. Ex. 10.

87. The label for APS Beta Alanine states “Clinically proven to increase muscle carnosine levels a critical fatigue controlling factor.” *Id.*

88. The label for APS Beta Alanine states “Boosts muscular anaerobic endurance.” *Id.*

89. The label for APS Beta Alanine states “Lactic acid elimination.” *Id.*

90. The label for APS Beta Alanine states “Increase exercise capacity so you can train harder and longer.” *Id.*

91. The supplement fact panel states “This nonessential amino acid increases the lactate threshold, which is the limiting factor in most training sessions. The build-up of lactic acid often prevents you from reaching your strength goals as your muscles begin to fatigue. With Beta-Alanine your training threshold is increased and your limitations can finally be broken down. Beta-Alanine can help increase your training capacity allowing you to train harder, stronger and longer than your last workout. Push through every rep and increase that weight! Beta-Alanine can improve muscular strength and endurance to provide a more powerful training session.” *Id.*

1           92. APS states on the website for APS Beta Alanine that “BETA ALANINE  
2 is a non-essential amino acid that is used by muscle cells to synthesize carnosine.  
3 Carnosine is a dipeptide (BETA ALANINE plus Histidine) that functions as a buffer  
4 for hydrogen ions (acid) produced during strenuous exercise, thus helping to maintain  
5 optimum muscular pH levels. APS uses CarnoSyn, a patented form of BETA  
6 ALANINE that has been clinically researched and gives nutritional support for  
7 muscles to work harder and longer during intense exercise.” *Id.*

8           93. APS also states on the website for APS Beta Alanine that “If you want  
9 your muscles to remain strong and maintain powerful contractions, they need to be in  
10 an optimal pH range. If they don’t and the pH drops below the optimal level, you have  
11 significantly less strength and you will fatigue more quickly. You know this is  
12 happening when you feel that familiar burn in your muscles or even when you’re  
13 lifting heavy and reach muscular failure. Muscle pH drops and it’s largely a result of  
14 an increase in hydrogen ions (H<sup>+</sup>) which build up when you break down the high  
15 energy compound ATP during exercise. Wouldn’t it be nice to knock out a few more  
16 reps? If you had more carnosine in your muscles, you would. Without it, your energy  
17 and endurance decline rapidly and your strength suffers. The breakdown of ATP and  
18 the subsequent rise in H<sup>+</sup> concentrations occurs in all of our energy systems but is  
19 most prevalent in an energy system called glycolysis which also produces lactic acid.  
20 Lactic acid releases H<sup>+</sup> ions, contributing further to the pool of H<sup>+</sup> that’s filling your  
21 muscles from the breakdown of ATP. With the presence of Hydrogen ions, pH drops  
22 fast as does muscular performance. High muscle carnosine levels help promote a  
23 dramatic increase in muscular strength, size, and endurance. Harness the power of  
24 BETA ALANINE and help maximize your workout performance and intensity!” *Id.*

25           94. On information and belief, and as a reasonable opportunity for further  
26 investigation or discovery will show, APS Beta Alanine contains beta-alanine  
27 obtained from another source.

1           95. APS infringes claim 1 of the '084 patent because it sells, and offers for  
2 sale, APS Beta Alanine which is a human dietary supplement that contains between  
3 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, per unit  
4 dosage.

5           96. APS makes statements in association with the use and promotion of its  
6 APS Beta Alanine product that induce infringement of at least claim 1 of the '596  
7 patent. For example, the label for APS Beta Alanine states that it is "Clinically proven  
8 to increase muscle carnosine levels a critical fatigue controlling factor," and "Lactic  
9 acid elimination" and the supplement fact panel states "This nonessential amino acid  
10 increases the lactate threshold, which is the limiting factor in most training sessions.  
11 The build-up of lactic acid often prevents you from reaching your strength goals as  
12 your muscles begin to fatigue. With Beta-Alanine your training threshold is increased  
13 and your limitations can finally be broken down." The website on which APS sells  
14 and promotes APS Beta Alanine states "BETA ALANINE is a non-essential amino  
15 acid that is used by muscle cells to synthesize carnosine. Carnosine is a dipeptide  
16 (BETA ALANINE plus Histidine) that functions as a buffer for hydrogen ions (acid)  
17 produced during strenuous exercise, thus helping to maintain optimum muscular pH  
18 levels. APS uses CarnoSyn, a patented form of BETA ALANINE that has been  
19 clinically researched and gives nutritional support for muscles to work harder and  
20 longer during intense exercise." *Id.*

21           97. APS infringes claim 1 of the '610 patent because it uses beta-alanine in  
22 manufacturing APS Beta Alanine, which is a human dietary supplement for oral  
23 consumption by supplying the beta-alanine, which is not exclusively obtained from  
24 NAI, in a manufacturing step of the APS Beta Alanine, which is for oral consumption  
25 in doses over a period of time to increase carnosine content in muscle tissue to delay  
26 the onset of fatigue in a human.



1 beneficial during high-intensity exercise and strength training and may help build lean  
2 muscle mass. It can also delay muscle fatigue, especially in older individuals.” *Id.*

3 103. APS Mesomorph contains creatine. *Id.*

4 104. The label for APS Mesomorph states “Lactic acid elimination.” *Id.*

5 105. APS Mesomorph is not marked with NAI’s patents or the CarnoSyn®  
6 trademark. *Id.*

7 106. Under the Agreement, Licensed Products, *i.e.*, those products containing  
8 only beta-alanine obtained from NAI, shall be marked with the CarnoSyn® trademark  
9 and NAI’s patents. Ex. 5 at ¶ 4.

10 107. On information and belief, and as a reasonable opportunity for further  
11 investigation or discovery will show, APS does not mark APS Mesomorph with  
12 NAI’s patents or the CarnoSyn® trademark because it contains beta-alanine obtained  
13 from another source.

14 108. APS infringes claim 1 of the ‘084 patent because it sells APS  
15 Mesomorph, which is a human dietary supplement that contains between 0.4 and 16 g  
16 of beta-alanine, which is not exclusively obtained from NAI, per unit dosage.

17 109. APS infringes claim 2 of the ‘084 patent because it sells APS  
18 Mesomorph, which is a human dietary supplement that contains between 0.4 and 16 g  
19 of beta-alanine, which is not exclusively obtained from NAI, and creatine per unit  
20 dosage.

21 110. APS makes statements in association with the use and promotion of its  
22 APS Mesomorph product that induce infringement of at least claim 1 of the ‘596  
23 patent. For example, the label for APS Mesomorph states that it is used for “Lactic  
24 acid elimination.” Additionally, the website on which APS promotes and sells APS  
25 Mesomorph states “Beta-alanine is a non-essential amino acid that will help improve  
26 exercise capacity and athletic performance. it is especially beneficial during high-  
27 intensity exercise and strength training and may help build lean muscle mass. It can  
28

1  
2 also delay muscle fatigue, especially in older individuals.” *Id.* Also, APS states on the  
3 website on which it promotes and sells APS Beta Alanine that “BETA ALANINE is a  
4 non-essential amino acid that is used by muscle cells to synthesize carnosine.  
5 Carnosine is a dipeptide (BETA ALANINE plus Histidine) that functions as a buffer  
6 for hydrogen ions (acid) produced during strenuous exercise, thus helping to maintain  
7 optimum muscular pH levels. APS uses CarnoSyn, a patented form of BETA  
8 ALANINE that has been clinically researched and gives nutritional support for  
9 muscles to work harder and longer during intense exercise.”

10 111. APS infringes claim 1 of the ‘610 patent because it uses beta-alanine in  
11 manufacturing APS Mesomorph, which is a human dietary supplement for oral  
12 consumption by mixing the beta-alanine, which is not exclusively obtained from NAI,  
13 in combination with at least one other ingredient for the manufacture of the APS  
14 Mesomorph, which is for oral consumption in doses over a period of time to increase  
15 carnosine content in muscle tissue to delay the onset of fatigue in a human.

16 112. APS infringes claim 5 of the ‘610 patent because it uses beta-alanine,  
17 which is not exclusively obtained from NAI, and at least one other ingredient in  
18 manufacturing the APS Mesomorph.

19 113. APS infringes claim 6 of the ‘610 patent because it uses beta-alanine,  
20 which is not exclusively obtained from NAI, and creatine in manufacturing the APS  
21 Mesomorph.

22 114. APS makes statements in association with the use and promotion of its  
23 APS Mesomorph product that induce infringement of at least claim 1 of the ‘865  
24 patent. The website that promotes APS Mesomorph states “Beta-alanine is a non-  
25 essential amino acid that will help improve exercise capacity and athletic  
26 performance. it is especially beneficial during high-intensity exercise and strength  
27 training and may help build lean muscle mass. It can also delay muscle fatigue,  
28



1 especially in older individuals.” *Id.* Also, APS states on the website on which it  
2 promotes and sells APS Beta Alanine that “BETA ALANINE helps provide the  
3 nutritional stimulus to increase anaerobic and aerobic endurance,” beta-alanine  
4 “supports increased performance and lean mass gains by: . . . increasing exercise  
5 capacity,” and “BETA ALANINE is a non-essential amino acid that is used by muscle  
6 cells to synthesize carnosine. Carnosine is a dipeptide (BETA ALANINE plus  
7 Histidine) that functions as a buffer for hydrogen ions (acid) produced during  
8 strenuous exercise, thus helping to maintain optimum muscular pH levels. APS uses  
9 CarnoSyn, a patented form of BETA ALANINE that has been clinically researched  
10 and gives nutritional support for muscles to work harder and longer during intense  
11 exercise.” Ex. 10.

#### 12 **6. APS MesomorphV.2.0**

13 115. One of the products APS promotes and sells is APS MesomorphV.2.0 on  
14 the website [http://www.apsnutrition.com/collections/all-products/products/](http://www.apsnutrition.com/collections/all-products/products/mesomorph-v-2-0)  
15 [mesomorph-v-2-0](http://www.apsnutrition.com/collections/all-products/products/mesomorph-v-2-0), which is incorporated by reference.

16 116. APS MesomorphV.2.0 is a human dietary supplement that contains beta-  
17 alanine in a proprietary blend of three ingredients. Ex. 12.

18 117. On the website selling and promoting APS MesomorphV.2.0, APS states  
19 that “Mesomorph™ V2.0 utilizes exclusive, premium ingredients like Creatine  
20 Nitrate, Creatinol-O-Phosphate, and over 4000mg of beta alanine and over 5000mg of  
21 citrulline malate.” *Id.*

22 118. The website also states “Beta-alanine is a non-essential amino acid that  
23 will help improve exercise capacity and athletic performance. It is especially  
24 beneficial during high-intensity exercise and strength training and may help build lean  
25 muscle mass. It can also delay muscle fatigue, especially in older individuals.” *Id.*

26 119. APS MesomorphV.2.0 contains creatine. *Id.*

27 120. The label for APS MesomorphV.2.0 states “Lactic acid elimination.” *Id.*



121. APS MesomorphV 2.0 is not marked with NAI's patents or the CarnoSyn® trademark. *Id.*

122. Under the Agreement, Licensed Products, *i.e.*, those products containing only beta-alanine obtained from NAI, shall be marked with the CarnoSyn® trademark and NAI's patents. Ex. 5 at ¶ 4.

123. On information and belief, and as a reasonable opportunity for further investigation or discovery will show, APS does not mark APS MesomorphV 2.0 with NAI's patents or the CarnoSyn® trademark because it contains beta-alanine obtained from another source.

124. APS infringes claim 1 of the '084 patent because it sells APS MesomorphV.2.0, which is a human dietary supplement that contains between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, per unit dosage.

125. APS infringes claim 2 of the '084 patent because it sells APS MesomorphV.2.0, which is a human dietary supplement that contains between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, and creatine per unit dosage.

126. APS makes statements in association with the use and promotion of its APS MesomorphV.2.0 product that induce infringement of at least claim 1 of the '596 patent. For example, the label for APS MesomorphV.2.0 states that it is used for "Lactic acid elimination." Additionally, the website on which APS promotes and sells APS MesomorphV.2.0 states "Beta-alanine is a non-essential amino acid that will help improve exercise capacity and athletic performance. It is especially beneficial during high-intensity exercise and strength training and may help build lean muscle mass. It can also delay muscle fatigue, especially in older individuals." *Id.* Also, APS states on the website on which it promotes and sells APS Beta Alanine that "BETA ALANINE is a non-essential amino acid that is used by muscle cells to synthesize carnosine. Carnosine is a dipeptide (BETA ALANINE plus Histidine) that functions as a buffer

1 for hydrogen ions (acid) produced during strenuous exercise, thus helping to maintain  
2 optimum muscular pH levels. APS uses CarnoSyn, a patented form of BETA  
3 ALANINE that has been clinically researched and gives nutritional support for  
4 muscles to work harder and longer during intense exercise.”

5 127. APS infringes claim 1 of the ‘610 patent because it uses beta-alanine in  
6 manufacturing APS MesomorphV.2.0, which is a human dietary supplement for oral  
7 consumption by mixing the beta-alanine, which is not exclusively obtained from NAI,  
8 in combination with at least one other ingredient for the manufacture of the APS  
9 MesomorphV.2.0, which is for oral consumption in doses over a period of time to  
10 increase carnosine content in muscle tissue to delay the onset of fatigue in a human.

11 128. APS infringes claim 5 of the ‘610 patent because it uses beta-alanine,  
12 which is not exclusively obtained from NAI, and at least one other ingredient in  
13 manufacturing the APS MesomorphV.2.0.

14 129. APS infringes claim 6 of the ‘610 patent because it uses beta-alanine,  
15 which is not exclusively obtained from NAI, and creatine in manufacturing the APS  
16 MesomorphV.2.0.

17 130. APS makes statements in association with the use and promotion of its  
18 APS MesomorphV 2.0 product that induce infringement of at least claim 1 of the ‘865  
19 patent. The website that promotes APS MesomorphV 2.0 states “Beta-alanine is a  
20 non-essential amino acid that will help improve exercise capacity and athletic  
21 performance it is especially beneficial during high-intensity exercise, strength training  
22 and may help build lean muscle mass. It can also delay muscle fatigue, especially in  
23 older individuals.” *Id.* Also, APS states on the website on which it promotes and sells  
24 APS Beta Alanine that “BETA ALANINE helps provide the nutritional stimulus to  
25 increase anaerobic and aerobic endurance,” beta-alanine “supports increased  
26 performance and lean mass gains by: . . . increasing exercise capacity,” and “BETA  
27 ALANINE is a non-essential amino acid that is used by muscle cells to synthesize  
28

1 carnosine. Carnosine is a dipeptide (BETA ALANINE plus Histidine) that functions  
2 as a buffer for hydrogen ions (acid) produced during strenuous exercise, thus helping  
3 to maintain optimum muscular pH levels. APS uses CarnoSyn, a patented form of  
4 BETA ALANINE that has been clinically researched and gives nutritional support for  
5 muscles to work harder and longer during intense exercise.” Ex. 10.

## 6 **7. Endurance BCAA Plus**

7 131. Hi-Tech, doing business as Formutech Nutrition (“Formutech”), sells and  
8 promotes products through its website, which is linked to the Hi-Tech  
9 Pharmaceuticals website. One of the products Formutech promotes and sells is  
10 Endurance BCAA Plus on the website  
11 [http://formutechnutrition.com/collections/recovery/products/endurance-bcaa-](http://formutechnutrition.com/collections/recovery/products/endurance-bcaa-plus?variant=7579799813)  
12 [plus?variant=7579799813](http://formutechnutrition.com/collections/recovery/products/endurance-bcaa-plus?variant=7579799813), which is incorporated by reference.

13 132. Endurance BCAA Plus is a human dietary supplement that contains 2 g  
14 of beta-alanine, identified as CarnoSyn® per dosage. Ex. 13.

15 133. Endurance BCAA Plus contains creatine. *Id.*

16 134. On the website promoting and selling Endurance BCAA it states “Beta  
17 Alanine increases muscle carnosine which help reduce muscle acids decreasing the  
18 burning sensation therefore delaying fatigue.” *Id.*

19 135. On information and belief, and as a reasonable opportunity for further  
20 investigation or discovery will show, Endurance BCAA Plus contains beta-alanine  
21 obtained from another source.

22 136. Formutech infringes claim 1 of the ‘084 patent because it sells, and offers  
23 for sale, Endurance BCAA Plus, which is a human dietary supplement that contains  
24 between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, per  
25 unit dosage.

26 137. Formutech infringes claim 2 of the ‘084 patent because it sells, and offers  
27 for sale, Endurance BCAA Plus, which is a human dietary supplement that contains  
28

1 between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI,  
2 and creatine per unit dosage.

3 138. Formutech makes statements in association with the use and promotion  
4 of its Endurance BCAA Plus product that induce infringement of at least claim 1 of  
5 the '596 patent. For example, Formutech states on its website that "Beta Alanine  
6 increases muscle carnosine which help reduce muscle acids decreasing the burning  
7 sensation therefore delaying fatigue."

8 139. Formutech infringes claim 1 of the '610 patent because it uses beta-  
9 alanine in manufacturing Endurance BCAA Plus, which is a human dietary  
10 supplement for oral consumption by mixing the beta-alanine, which is not exclusively  
11 obtained from NAI, in combination with at least one other ingredient for the  
12 manufacture of the APS Mesomorph, which is for oral consumption in doses over a  
13 period of time to increase carnosine content in muscle tissue to delay the onset of  
14 fatigue in a human.

15 140. Formutech infringes claim 5 of the '610 patent because it uses beta-  
16 alanine, which is not exclusively obtained from NAI, and at least one other ingredient  
17 in manufacturing the Endurance BCAA Plus.

18 141. Formutech infringes claim 6 of the '610 patent because it uses beta-  
19 alanine, which is not exclusively obtained from NAI, and creatine in manufacturing  
20 the Endurance BCAA Plus.

## 21 **8. Volatile Pre-Workout**

22 142. One of the products Formutech promotes and sells is Volatile Pre-  
23 Workout on the website [http://formutechnutrition.com/collections/gain-muscle/](http://formutechnutrition.com/collections/gain-muscle/products/volatile-pre-workou?variant=7581642821)  
24 [products/volatile-pre-workou?variant=7581642821](http://formutechnutrition.com/collections/gain-muscle/products/volatile-pre-workou?variant=7581642821), which is incorporated by  
25 reference.

26 143. Volatile Pre-Workout is a human dietary supplement that contains beta-  
27 alanine, identified as CarnoSyn®. Ex. 14.

144. Volatile Pre-Workout contains creatine. *Id.*

145. Volatile Pre-Workout contains carbohydrate. *Id.*

146. Volatile Pre-Workout does not contain L-histidine. *Id.*

147. Volatile Pre-Workout is a human dietary supplement that is formulated for one or more doses per day for at least 14 days. *Id.*

148. On information and belief, and as a reasonable opportunity for further investigation or discovery will show, Volatile Pre-Workout contains beta-alanine obtained from another source.

149. Formutech infringes claim 1 of the '084 patent because it sells, and offers for sale, Volatile Pre-Workout which is a human dietary supplement that contains between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, per unit dosage.

150. Formutech infringes claim 2 of the '084 patent because it sells, and offers for sale, Volatile Pre-Workout which is a human dietary supplement that contains between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, and creatine per unit dosage.

151. Formutech infringes claim 34 of the '947 patent because it sells, and offers for sale, Volatile Pre-Workout which contains beta-alanine, which is not exclusively obtained from NAI, between 0.4 and 16 grams per daily dose, creatine and carbohydrate, does not contain L-histidine and is formulated for one or more doses per day for at least 14 days.

## **9. Wicked Pre-Workout**

152. Hi-Tech, doing business as Innovative Laboratories ("Innovative"), is linked to the Hi-Tech Pharmaceuticals website and promotes and sells products. One of the products it promotes and sells is Wicked Pre-Workout on the website <http://innovativelaboratories.net/collections/pre-workouts/products/wicked-pre-workout>, which is incorporated by reference.

153. Wicked Pre-Workout is a human dietary supplement that contains beta-alanine. Ex. 15.

154. Wicked Pre-Workout contains creatine. *Id.*

155. Wicked Pre-Workout contains carbohydrate. *Id.*

156. Wicked Pre-Workout is not marked with NAI's patents or the CarnoSyn® trademark. *Id.*

157. Under the Agreement, Licensed Products, *i.e.*, those products containing only beta-alanine obtained from NAI, shall be marked with the CarnoSyn® trademark and NAI's patents. Ex. 5 at ¶ 4.

158. On information and belief, and as a reasonable opportunity for further investigation or discovery will show, Innovative does not mark Wicked Pre-Workout with NAI's patents or the CarnoSyn® trademark because it contains beta-alanine obtained from another source.

159. Innovative infringes claim 1 of the '084 patent because it sells Wicked Pre-Workout, which is a human dietary supplement that contains between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, per unit dosage.

160. Innovative infringes claim 2 of the '084 patent because it sells Wicked Pre-Workout, which is a human dietary supplement that contains between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, and creatine per unit dosage.

#### **10. Products Manufactured By Hi-Tech For Others**

161. As alleged above, Hi-Tech not only sells its own products but also acts as a contract manufacturer for other dietary supplement brand companies. Hi-Tech manufactures and sells dietary supplements containing beta-alanine. It has imported or purchased the raw material beta-alanine from others, and not NAI.

1 162. By way of example, Hi-Tech has manufactured dietary supplements  
2 containing beta-alanine for its customer, Muscle Elements (“ME”), without using  
3 CarnoSyn® beta-alanine purchased from NAI.

4 163. ME is not a licensee of NAI nor has Hi-Tech informed NAI that it used  
5 or intended to use CarnoSyn® beta-alanine to make product for ME.

6 164. ME sells and promotes products through its website. One of the products  
7 ME promotes and sells is PreCre on the website [http://www.muscle-elements.com/](http://www.muscle-elements.com/precre)  
8 precre, which is incorporated by reference.

9 165. PreCre is a human dietary supplement that contains 1.2 g of beta-alanine  
10 per dosage. Ex. 16.

11 166. PreCre is a human dietary supplement that contains 5 g of creatine per  
12 dosage. *Id.*

13 167. PreCre is a human dietary supplement that contains carbohydrate. *Id.*

14 168. PreCre is a human dietary supplement that does not contain L-histidine.  
15 *Id.*

16 169. PreCre is a human dietary supplement that is formulated for one or more  
17 doses per day for at least 14 days. *Id.*

18 170. The label for PreCre identifies CarnoSyn® as NAI’s trademark and that  
19 the product is licensed under one or more patents owned by NAI, including the ‘596  
20 patent. *Id.*

21 171. ME states on the website for PreCre that “CarnoSyn® (Beta alanine) - an  
22 amino acid that along with histidine makes up carnosine, an amino acid found in  
23 muscle. Carnosine plays a role in contractile behavior of muscle and reduces fatigue\*.  
24 Beta alanine supplementation, the rate limiting precursor of carnosine, actually  
25 increases muscle carnosine content, exercise capacity, endurance, muscle force  
26 production, lean body mass, and decreases fatigue by buffering hydrogen ions\*. Beta  
27 alanine dosages of 1.6 grams have been shown to enhance carnosine, endurance and  
28



1 muscle force production\*. PreCre contains 1.2 grams of beta-alanine per serving/ per  
2 scoop.” *Id.*

3 172. ME infringes claim 1 of the ‘084 patent because it sells, and offers for  
4 sale, PreCre which is a human dietary supplement that contains between 0.4 and 16 g  
5 of beta-alanine, which is not exclusively obtained from NAI, per unit dosage.

6 173. ME infringes claim 2 of the ‘084 patent because it sells, and offers for  
7 sale, PreCre which is a human dietary supplement that contains between 0.4 and 16 g  
8 of beta-alanine, which is not exclusively obtained from NAI, and creatine per unit  
9 dosage.

10 174. ME makes statements in association with the use and promotion of its  
11 PreCre product that induce infringement of at least claim 1 of the ‘596 patent. For  
12 example, the website on which ME sells and promotes PreCre states “Beta alanine  
13 supplementation, the rate limiting precursor of carnosine, actually increases muscle  
14 carnosine content, exercise capacity, endurance, muscle force production, lean body  
15 mass, and decreases fatigue by buffering hydrogen ions.” *Id.*

16 175. ME infringes claim 34 of the ‘947 patent because it sells, and offers for  
17 sale, PreCre which contains beta-alanine, which is not exclusively obtained from NAI,  
18 between 0.4 and 16 grams per daily dose, creatine and carbohydrate, does not contain  
19 L-histidine and is formulated for one or more doses per day for at least 14 days.

20 176. Hi-Tech infringes claim 1 of the ‘610 patent because it uses unlicensed  
21 beta-alanine in manufacturing PreCre for ME, which is a human dietary supplement  
22 for oral consumption by mixing the beta-alanine, which is not exclusively obtained  
23 from NAI, in combination with at least one other ingredient for the manufacture of the  
24 PreCre, which is for oral consumption in doses over a period of time to increase  
25 carnosine content in muscle tissue to delay the onset of fatigue in a human.

26 177. Hi-Tech infringes claim 5 of the ‘610 patent because it uses unlicensed  
27 beta-alanine, which is not exclusively obtained from NAI, and at least one other  
28 ingredient in manufacturing the PreCre for ME.

1 178. Hi-Tech infringes claim 6 of the '610 patent because it uses unlicensed  
2 beta-alanine, which is not exclusively obtained from NAI, and creatine in  
3 manufacturing the PreCre for ME.

4 179. Another product ME promotes and sells is PreCre XS on the website  
5 <http://www.muscle-elements.com/precre-xs>, which is incorporated by reference.

6 180. PreCre XS is a human dietary supplement that contains 2.0 g of beta-  
7 alanine per dosage. Ex. 17.

8 181. PreCre XS is a human dietary supplement that contains 5 g of creatine  
9 per dosage. *Id.*

10 182. PreCre XS is a human dietary supplement that contains carbohydrate. *Id.*

11 183. PreCre XS is a human dietary supplement that does not contain L-  
12 histidine. *Id.*

13 184. PreCre XS is a human dietary supplement that is formulated for one or  
14 more doses per day for at least 14 days. *Id.*

15 185. The label for PreCre identifies CarnoSyn® as NAI's trademark and that  
16 the product is licensed under one or more patents owned by NAI, including the '596.  
17 *Id.*

18 186. ME states on the website for PreCre XS that "CarnoSyn® (Beta  
19 alanine) - an amino acid that along with histidine makes up carnosine, an amino acid  
20 found in muscle. Carnosine plays a role in contractile behavior of muscle and reduces  
21 fatigue\*. Beta alanine supplementation, the rate limiting precursor of carnosine,  
22 actually increases muscle carnosine content, exercise capacity, endurance, muscle  
23 force production, lean body mass, and decreases fatigue by buffering hydrogen ions\*.  
24 Beta alanine dosages of 1.6 grams have been shown to enhance carnosine, endurance  
25 and muscle force production\*. PreCre XS contains 2 grams of beta-alanine per  
26 serving/ per scoop." *Id.*

187. ME infringes claim 1 of the '084 patent because it sells, and offers for sale, PreCre XS which is a human dietary supplement that contains between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, per unit dosage.

188. ME infringes claim 2 of the '084 patent because it sells, and offers for sale, PreCre XS which is a human dietary supplement that contains between 0.4 and 16 g of beta-alanine, which is not exclusively obtained from NAI, and creatine per unit dosage.

189. ME makes statements in association with the use and promotion of its PreCre XS product that induce infringement of at least claim 1 of the '596 patent. For example, the website on which ME sells and promotes PreCre XS states "Beta alanine supplementation, the rate limiting precursor of carnosine, actually increases muscle carnosine content, exercise capacity, endurance, muscle force production, lean body mass, and decreases fatigue by buffering hydrogen ions." *Id.*

190. ME infringes claim 34 of the '947 patent because it sells, and offers for sale, PreCre XS which contains beta-alanine, which is not exclusively obtained from NAI, between 0.4 and 16 grams per daily dose, creatine and carbohydrate, does not contain L-histidine and is formulated for one or more doses per day for at least 14 days.

191. Hi-Tech infringes claim 1 of the '610 patent because it uses unlicensed beta-alanine in manufacturing PreCre XS for ME, which is a human dietary supplement for oral consumption by mixing the beta-alanine, which is not exclusively obtained from NAI, in combination with at least one other ingredient for the manufacture of the PreCre, which is for oral consumption in doses over a period of time to increase carnosine content in muscle tissue to delay the onset of fatigue in a human.

192. Hi-Tech infringes claim 5 of the '610 patent because it uses unlicensed beta-alanine, which is not exclusively obtained from NAI, and at least one other ingredient in manufacturing the PreCre XS for ME.

193. Hi-Tech infringes claim 6 of the '610 patent because it uses unlicensed beta-alanine, which is not exclusively obtained from NAI, and creatine in manufacturing the PreCre XS for ME.

**F. HI-TECH'S ACTS OF TRADEMARK INFRINGEMENT**

194. Hi-Tech promotes and sells products, APS Beta-Alanine, Endurance BCAA Plus and Volatile Pre-Workout, using NAI's CarnoSyn® trademark. *See, e.g.*, Exs. 10, 13, 14.

195. Hi-Tech is not authorized to use NAI's trademarks unless the products contain CarnoSyn® beta-alanine purchased from NAI. On information and belief, these three products were not made using CarnoSyn®, or beta-alanine exclusively obtained from NAI. Hi-Tech did not mark its Endurance BCAA Plus and Volatile Pre-Workout products with applicable NAI patent numbers or virtual mark them, as required by paragraph 4 of the Agreement. The three products were not licensed products under the Agreement and Hi-Tech was not authorized to use NAI's trademark on them.

196. The documents referred to herein are incorporated by reference.

**COUNT I**

**(Breach of Contract)**

197. The foregoing factual allegations in paragraphs 1-196 are incorporated by reference.

198. Hi-Tech breached paragraph 10 of the Agreement by failing to allow NAI to audit Hi-Tech's records.

199. Hi-Tech breached paragraph 4 of the Agreement by not marking any of its products containing CarnoSyn® beta-alanine with the applicable NAI patent numbers or by not virtually marking the products under 35 U.S.C. § 287.

200. As such, Hi-Tech has materially breached paragraphs 4 and 10 of the Agreement.



209. This claim encompasses accused products that do not contain CarnoSyn® beta-alanine or that contain some CarnoSyn® beta-alanine comingled with beta-alanine purchased from a supplier other than NAI.

210. Hi-Tech's infringement has been willful.

211. NAI has been irreparably harmed by Hi-Tech's acts of infringement and has suffered damages in an amount to be determined at trial.

### COUNT III

**(Lanham Act § 32)**

212. The foregoing factual allegations in paragraphs 1-196 are incorporated by reference.

213. Hi-Tech's products are used, sold, and/or offered for sale in interstate and foreign commerce.

214. In connection with its goods or services, including its APS Beta-Alanine, Endurance BCAA and Volatile Pre-Workout products, Hi-Tech has used a reproduction, counterfeit, copy, or colorable imitation of NAI's registered trademark without NAI's consent, knowing that such act is intended to be used to cause confusion, or to cause mistake, or to deceive.

215. Hi-Tech knowingly and willfully misrepresented to the public, *inter alia*, the facts alleged above.

216. By reason of Hi-Tech's statements and conduct, Hi-Tech has willfully violated section 32 of the Lanham Act, 15 U.S.C. § 1114, and NAI has suffered, and will continue to suffer damage to its business, reputation, and good will and has lost sales and profits that it would have made but for Hi-Tech's acts.

217. NAI has been irreparably harmed by Hi-Tech's acts in violation of the Lanham Act and has suffered damages in an amount to be determined at trial.

**REQUEST FOR RELIEF**

NAI respectfully requests that this Court enter judgment against Hi-Tech and that the following relief be granted:

- a. judgment that Hi-Tech has materially breached paragraphs 4 and 10 of the Agreement;
- b. judgment against Hi-Tech for damages plus pre- and post-judgment interest;
- c. a preliminary and permanent injunction against Hi-Tech and those acting in concert with it to comply with the provisions of the Agreement;
- d. imposing a constructive trust;
- e. an accounting;
- f. payment of reasonable attorneys' fees as allowed by the Agreement and law;
- g. judgment that Hi-Tech has infringed one or more claims of the patents-in-suit;
- h. judgment that Hi-Tech's infringement of one or more claims of the patents-in-suit was willful;
- i. injunction against continued infringement (35 U.S.C. § 283);
- j. damages for past infringement (35 U.S.C. § 284);
- k. imposition of a constructive trust on all proceeds from the sale of accused products;
- l. increased and trebled damages for willful infringement (35 U.S.C. § 284);
- m. judgment that Hi-Tech has violated section 32 of the Lanham Act;
- n. judgment for compensatory, treble damages and statutory damages;
- o. a preliminary and permanent injunction against continued violations of the Lanham Act;



- 1 p. attorneys' fees as allowed by law, including without limitation, 15 U.S.C.  
2 § 1117(a);  
3 q. costs pursuant to Fed. R. Civ. P. 54(d) or otherwise provided by law; and  
4 r. such other relief as the Court deems just and appropriate under the  
5 circumstances.

6 **JURY DEMAND**

7 NAI hereby demands a jury trial on all issues so triable.

8  
9 Dated: October 31, 2016

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