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

HI-TECH PHARMACEUTICALS, INC., : and INTELLECTUAL WELLNESS, :

LLC,

:

Plaintiffs,

:

vs. : CIVIL ACTION FILE NO:

1:15-cv-3887-RWS

IRONMAGLABS, LLC. A Nevada

Limited Liability Company and ROBERT DIMAGGIO :

:

Defendants. :

COMPLAINT

COMES NOW, the Plaintiffs Hi-Tech Pharmaceuticals, Inc., ("Hi-Tech") and Intellectual Wellness, LLC, ("Intellectual Wellness") (collectively "Plaintiffs"), by and through the undersigned counsel of record, and for its Complaint against the Defendants IronMag Labs, LLC, ("IronMag") and Robert Dimaggio ("Dimaggio,") (collectively IronMag and Mr. Dimaggio shall be referred to as "Defendants"), states as follows:

I. THE PARTIES

1. Hi-Tech is a corporation organized and existing under the laws of the State of Georgia, with its principal place of business located at 6015-B Unity Drive, Norcross, Georgia 30071. Hi-Tech sells, distributes, and manufactures high quality

dietary supplement products in the State of Georgia and throughout the United States.

- 2. Intellectual Wellness is a Michigan Limited Liability Company with its principle place of business in Brighton, Michigan
- 3. Intellectual Wellness is the owner by assignment of the following United States Patent: U.S. Patent No. 8,084,446, entitled "Use of DHEA Derivatives for Enhancing Physical Performance" ("the '446 patent") (attached thereto as Exhibit A).
- 4. Intellectual Wellness is the owner by assignment of the following United States Patent: U.S. Patent No. 8,338,399 entitled "Use of DHEA Derivatives for Enhancing Physical Performance" ("the '399 patent") (attached thereto as Exhibit B).
- 5. The above patents are herein referred to as the "Patents in Suit"
- 6. Hi-Tech has been granted a license to the Patents in Suit by Intellectual Wellness which includes the right to institute suit with the respect to infringement of the Patents in Suit.
- 7. Defendant IronMag is a Nevada Limited Liability Company with its principal place of business located in Las Vegas, Nevada. Upon information and belief, IronMag sells, distributes, and markets its products, including the Infringing

Products at issue, in the State of Georgia, in this District, and throughout the United States.

- 8. Mr. Dimaggio is an individual and citizen of Michigan.
- 9. Upon information and belief, Dimaggio is the Chief Executive Officer, owner, and President of IronMag.
- 10. Upon information and belief, Mr. Dimaggio authorizes, participates in, directs, controls, causes, ratifies, and/or is the moving force behind the selection and sale and distribution of the Infringing Products and/or personally sells the Infringing Products.

II. JURISDICTION AND VENUE

- 11. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code.
- 12. Accordingly, this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338 and 1367.
- 13. This is also an action under the Lanham Act, 15 U.S.C. § 1051, et. seq., and the Georgia Deceptive and Unfair Trade Practices Act, O.C.G.A. §10-1-372 (a), for relief from IronMag's false advertising, deceptive acts, and unfair competition arising out of IronMag's use of false or misleading descriptions and/or false or misleading representations of fact. Hi-Tech brings this action to enjoin IronMag from continuing to falsely advertise its dietary supplement products, and to recover

from the competitive injury that IronMag's false advertising and unfair competition have caused to Hi-Tech's business.

- 14. Accordingly, this Court has subject matter jurisdiction over this action pursuant to 15 U.S.C § 1331 (federal question).
- 15. This Court also has jurisdiction pursuant to 28 U.S.C § 1367 (supplemental jurisdiction), and 28 U.S.C. § 1332 (diversity), as this action is between citizens of different states and the amount in controversy, exclusive of interest and costs, exceeds seventy-five thousand dollars (\$75,000.00).
- 16. This Court has personal jurisdiction over Defendants. For example, this Court may exercise personal jurisdiction over the Defendants pursuant to O.C.G.A. §9-10-91 because one or more of the Defendants are doing business in this judicial district and/or have committed tortious acts within this judicial district including unfair competition, patent infringement, among other wrongful and unlawful acts.
- 17. This Court therefore has jurisdiction over the Defendants pursuant to the provisions of the Georgia long-arm statute.
- 18. Venue is proper under 28 U.S.C. §§1391 and 1400 in that one or more of the Defendants are doing and transacting business within this judicial district, and have committed the tortious acts complained of herein in this judicial district. By way of example and without limitation, Defendants directly or through intermediaries (including distributors, retailers, and others), formulates, makes, manufactures,

ships, distributes, advertises, markets, offers for sale, and/or sells dietary supplement products that infringe on one or more claims of the Patents in Suit (hereinafter the "Infringing Products"), which include without limitation products sold under the "4 Andro Rx" and "1 Andro Rx" brand names in the Northern District of Georgia.

- 19. By way of further example and without limitation, Defendants have purposefully and voluntarily placed the Infringing Products and illegal supplements into the stream of commerce with the knowledge, understanding, and expectation that such Infringing Products would and will be purchased in the Northern District of Georgia.
- 20. The Infringing Products were currently available for purchase in the Northern District of Georgia.
- 21. The Infringing Products are currently available for purchase in the Northern District of Georgia.

III. FACTUAL BACKGROUND

22. The nutritional supplement industry is one of the fastest growing and most lucrative in the United States. A recent Forbes article estimates that nutritional supplement sales accounted for \$32 billion in revenue in 2012 and predicts this number to grow to \$60 billion within ten years. The growth and size of the nutritional supplement market and the relatively low barriers to entry provide perverse incentives for unfair competition prohibited by the Lanham Act.

- 23. Hi-Tech is a cutting-edge sports supplement manufacturer and marketer. From its inception, Plaintiff has been a leader in the nutritional supplement market, specifically for body building products.
- 24. Hi-Tech manufactures and sells products in several categories of body building products, including testosterone boosters, muscle-gainers, and proanabolics.
- 25. Hi-Tech manufactures dozens of products in the testosterone boosters, muscle-gainers, and pro-anabolics sub-markets.
- 26. Defendants operate a dietary supplement company which provides sports nutrition, muscle enhancement, weight loss, pre-and post-workout, and other various supplements.
- 27. Defendants maintain a website at IronMagLabs.com to facilitate the sale and distribution of its products.
- 28. Defendants advertise and sell their dietary supplements, including the Infringing Products, nationwide, including within the Northern District of Georgia.
- 29. As early as May 1, of 2012 Defendants were on notice of their infringement of the Patents in Suit; were notified to cease and desist their infringement of the patent rights under the Patents in Suit; and were on notice that certain products sold by Defendants infringed one or more of the claims of one or more of the patent rights of the Patents in Suit.

- 30. Defendants were sued for their infringement on September 25, 2014 in the United States District Court for the Eastern District of Michigan in an action entitled *Intellectual Wellness, LLC v. IronMag Labs, LLC* Civil Action No. 5:14-cv-13717-JEL-RSW (hereinafter "the Previous Action").
- 31. On December 12, 2014, Defendants acknowledged the Patent rights under the Patents in Suit when they settled the Previous Action and agreed to pay royalties for use of the Patents in Suit.
- 32. Notwithstanding their acknowledgement of the patent rights in the Patents in Suit, Defendants continued to, and still does, sell the Infringing Products and refuses and fails to pay the royalties agreed upon in settling the Previous Action.
- 33. Hi-Tech's body building products have natural ingredients and compete directly with Defendants' Super DMZ 4.0TM and Osta RxTM products.

DEFENDANTS' MISREPRESENTATIONS

34. Defendants have made deliberate and misleading representations regarding the IronMag Labs' Super DMZ 4.0TM and Osta RxTM products. These products are marketed as being natural supplements, when, in fact, they contain an illegal unapproved new drug known as Ostarine, or (2S)-3-(4-cyanophenoxy)-N-[4-cyano-3-(trifluoromethyl)phenyl]-2-hydroxy-2-methylpropanamide, which is a selective androgen receptor modulator for which substantial clinical investigations have been

instituted and made public with regard to treatment of cancer cachexia, or muscle wasting.

- 35. Super DMZ 4.0TM and Osta RxTM are androgenic modulator products and unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. §§ 355(a) and 331(d)] and are misbranded drugs sold in violation of sections 502 and 301(a) [21 U.S.C. §§ 352 and 331(a)] of the FDCA.
- 36. IronMag Labs states that that this product contains the following active pharmaceutical ingredients:

Product	Active Pharmaceutical Ingredient
Super DMZ	(2S)-3-(4-cyanophenoxy) -N- [4-cyano-3-(trifluoromethyl)phenyl] -2-
4.0^{TM}	methylpropanamide) Ostarine (MK-2866) (declared on the immediate container
	label)

37. IronMag Labs states that that this product contains the following active pharmaceutical ingredients:

Product	Active Pharmaceutical Ingredient
Osta Rx TM	(2S)-3-(4-cyanophenoxy) -N- [4-cyano-3-(trifluoromethyl)phenyl] -2-methylpropanamide) Ostarine (MK-2866) (declared on the immediate container label)

38. Super DMX 4.0TM and Osta RxTM are not dietary supplements. According to section 201(ff)(3)(B)(i) of the FDCA [21 U.S.C. § 321 (ff)(3)(B)(i)], a dietary supplement may not include an article that is approved as a new drug under section 505 of the FDCA [21 U.S.C. § 355(a)] unless that article was marketed as a dietary

supplement or food prior to FDA approval of such drug. According to section 201(ff)(3)(B)(ii) of the FDCA [21 U.S.C. § 321 (ff)(3)(B)(ii)], a dietary supplement also may not include an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was marketed as a dietary supplement or food before its authorization as a new drug.

- 39. Super DMZTM 4.0 and Osta RxTM contain (2S)-3-(4-cyanophenoxy)-N-[4-cyano-3-(trifluoromethyl)phenyl]-2-hydroxy-2-methylpropanamide which is the subject of substantial clinical investigations, which have been made public (see Exhibit C).
- 40. Upon information and belief and based on the information available to Hi-Tech, ostarine was not marketed as a dietary supplement or as a food until after it was under substantial clinical investigation. Therefore, Super DMZ 4.0TM and Osta RxTM, which contain ostarine, are also excluded from the definition of a dietary supplement under section 201(ff)(3)(B)(ii) of the FDCA [21 U.S.C. § 321 (ff)(3)(B)(ii)].
- 41. Super DMZ 4.0TM and Osta RxTM are also classified as "new drugs" as defined by section 201(p) of the FDCA [21 U.S.C. § 321(p)], because these products are not generally recognized among experts as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

- 42. Furthermore, Super DMZ 4.0TM and Osta RxTM are prescription drugs as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], because due to their toxicity or potentiality for harmful effect, the method of their use, or the collateral measures necessary for their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer them. Super DMX 4.0TM and Osta RxTM are also prescription drugs because they contain a selective androgen receptor modulator, ostarine, and present significant potential safety risks to consumers who take them without the supervision of a practitioner licensed by law to administer such drugs.
- 43. Under sections 301(d) and 505(a) of the FDCA [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA approved application is in effect for it.
- 44. No approved applications are in effect for IronMag Labs Super DMZ 4.0^{TM} and Osta Rx^{TM} products.
- 45. Consequently, IronMag Labs' marketing and sale of these products without such approved applications violates these provisions of the FDCA.
- 46. According to section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)], a drug is misbranded if, among other things, it fails to bear adequate directions for its intended use(s).

- 47. "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended [21 CFR Part 201.5].
- 48. Prescription drugs can be used safely only at the direction, and under the supervision of a licensed practitioner and therefore, it is impossible to write "adequate directions for use" for prescription drugs.
- 49. FDA-approved prescription drugs which bear the FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson [21 CFR Part 201.100(c)(2) and 201.115].
- 50. Therefore, because there are no FDA-approved applications for IronMag's Super DMZ 4.0TM and Osta RxTM products, their labeling fail to bear adequate directions for their intended use, causing them to be misbranded under section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)].
- 51. IronMag's Super DMZ 4.0TM and Osta RxTM products are misbranded for all of the aforementioned reasons. The introduction or delivery for introduction into interstate commerce of these misbranded drug products violates section 301(a) of the FDCA [21 U.S.C. § 331(a)].
- 52. Defendants' false, misleading and deceptive practices have violated the Lanham Act and have unjustly enriched Defendants at the expense of Hi-Tech, and have caused Hi-Tech extensive and irreparable harm, including, but not limited to, loss of revenue, disparagement, and loss of goodwill.

DEFENDANTS' INFRINGEMENTS

- 53. Plaintiffs incorporate the foregoing paragraphs as if fully restated herein.
- 54. Defendants have committed the tort of patent infringement within the State of Georgia, and more particularly, within the Northern District of Georgia, in that Defendants have caused the Infringing Products to be formulated made, manufactured, shipped, distributed, advertised, offered for sale and/or sold in this District, and continues to do so.
- 55. The Infringing Products are formulated, made, manufactured, shipped, distributed, advertised, offered for sale and sold by Defendants to include certain ingredients that, by virtue of their inclusion in the Infringing Products, infringe one or more of the claims of the Patents in Suit.

A. <u>DIRECT INFRINGEMENTS</u>

- 56. Plaintiffs incorporate the foregoing paragraphs as if fully restated herein.
- 57. Defendants' employees, agents, representatives, and/or other persons sponsored by or who endorse Defendants and/or Defendants' Infringing Products in advertising and marketing activities, have taken, used, and orally administered the Infringing Products.
- 58. The Infringing Products are formulated, made, manufactured, shipped, distributed, advertised, offered for sale and sold by Defendants to include certain

ingredients that, by virtue of their inclusion in the Infringing Products, infringe one or more of the claims of the Patents in Suit.

- 59. The Infringing Products are and were formulated, made, manufactured, shipped, distributed, advertised, offered for sale and sold by Defendants by virtue of the inclusion in the Infringing Products of one or more claims of the Patents in Suit, infringes and infringed one or more of the claims of one or more of the Patents in Suit, and as a result, when Defendants' employees, agents, representatives, and/or other persons sponsored by or who endorse Defendants and/or Defendants' Infringing Products in advertising and marketing activities orally administer and administered the Infringing Products, they are and were practicing and practiced the methods disclosed in those claims.
- 60. The purposes for which these ingredients are included in the Infringing Products are and were, without limitation to enhance physical performance.
- 61. Defendants encouraged and/or is aware of the fact that its employees, agents, representatives, and/or other persons sponsored by or who endorse Defendants and/or Defendants' Infringing Products in advertising and marketing activities orally administered and administer the Infringing Products and practice and practiced the methods disclosed in one or more claim of the Patents in Suit, and these employees, agents, representatives, and/or other persons sponsored by or who endorse Defendants and/or Defendants' Infringing Products in advertising and marketing

activities are and were acting under Defendants' direction and control when practicing these methods.

62. Therefore, Defendants are and were a direct infringer of one or more claims of the Patents in Suit pursuant to 35 U.S.C. § 271(a).

B. INDIRECT INFRINGEMENTS

- 63. Plaintiffs incorporate the foregoing paragraphs as if fully restated herein.
- 64. End-users of Defendants' Infringing Products were and also still are direct infringers of one or more claims of the Patents in Suit. End-users of Defendants' Infringing Products have taken, used, and orally administered the Infringing Products.
- 65. The Infringing Products are and were formulated, made, manufactured, shipped, distributed, advertised, offered for sale and/or sold by Defendants by virtue of its inclusion in the Infringing Products, infringe and infringed one or more of the claims of the Patents in Suit, and as a result, when end-users of Defendants' Infringing Products orally administer and administered the Infringing Products, they are and were practicing and practiced the methods disclosed in those claims.
- 66. Defendants' labels and advertising for the Infringing Products explain and explained the elements and essential elements of one or more of the methods disclosed in the Patents in Suit, and those labels and advertising statements encourage, urge, and induce the Infringing Products' end-users and Defendants have

therefore specifically intended to cause these end-users to directly infringe the claimed methods of the Patents in Suit, and did so in the past, and to purchase and orally ingest the products to practice those methods, and end-users do and did practice those methods.

- 67. Defendants have therefore specifically intended to cause these end-users to directly infringe the claimed methods of the Patents in Suit, and in fact urged them to do so.
- 68. The Infringing Products are not and were not suitable for non-infringing uses, and none of Defendants' labels or advertisements for their Infringing Products disclose or disclosed any uses for the products, nor for the compounds disclosed in the claimed methods of the Patents in Suit, that do not infringe these claimed methods.
- 69. The inclusion of the specific infringing compounds in the Infringing Products is and was material to practicing such methods.
- 70. Defendants had knowledge that the Infringing Products are and were especially adapted by end-users of the products for the practicing of such methods, and indeed, Defendants encouraged, urged, and induced, and still encourages, urges and induces the Infringing Products' end-users to purchase and orally administer the Infringing Products to practice such methods.

- 71. Defendants intentionally and knowingly induced encouraged, urged, and induced, and still encourages, urges and induces the Infringing Products' end-users to purchase and orally administer the Infringing Products for the purpose of practicing the claimed methods of the Patents in Suit, by having them orally ingest the compounds disclosed in such claims.
- 72. Defendants have and had knowledge of the fact that the accused products, particularly as administered, infringe on one or more of the claims of the Patents in Suit.
- 73. Defendants have and had direct firsthand knowledge of the Patents in Suit since at least May of 2012.
- 74. Defendants willfully and knowingly decided to infringe the Patents in Suit despite knowledge of the patent's existence and its knowledge of the Infringing Products infringements of the claims of the Patents in Suit.
- 75. At a minimum, and in the alternative, Plaintiff pleads that the Defendants willfully blinded itself to the infringing nature of the Infringing Products' sales.
- 76. Defendants did not cease its own direct infringement, nor its contributory infringement or inducement of infringement by end-users, despite its knowledge of the Patents in Suit and the end-users' infringing activities with respect to the Patents in Suit.

77. Therefore, Defendants are and were a indirect infringer of one or more claims of the Patents in Suit pursuant to 35 U.S.C. § 271(b) and (c).

COUNT I INFRINGEMENT OF U.S. PATENT NO. 8,084,446

- 78. Plaintiffs incorporate the foregoing paragraphs as if fully restated herein.
- 79. Defendants have, and continue to do so, literally and directly infringed, or directly infringed under the doctrine of equivalents one or more claims of United States Patent No. 8,084,446 by making, using, offering to sell, and/or selling in the United States, and/or importing into the United States the Infringing Products, or any one of those products.
- 80. In addition to the fact Defendants makes, uses, sells, and/or offers for sale the Infringing Products, and did so in the past, further examples of Defendants' direct infringements include, without limitation, the fact that Defendants encouraged and/or was aware that its employees, agents, representatives, and/or other persons sponsored by or who endorse Defendants and/or Defendants' Infringing Products in advertising and marketing activities, orally administered the Infringing Products, and practiced and continue to practice the methods disclosed in one or more claim of the '446 Patent, and these employees, agents, representatives, and/or other persons sponsored by or who endorse Defendants and/or Defendants' Infringing Products in advertising and marketing activities were acting under Defendants' direction and control when practicing these methods.

- 81. Defendants encouraged and was aware of these persons' oral administration of the Infringing Products for these purposes, these persons were acting under Defendants direction and control, and therefore Defendants directly practiced the methods and/or claims of the '446 Patent.
- 82. End-users of Defendants' Infringing Products were also direct infringers of one or more claims of the '446 Patent.
- 83. End-users of Defendants' Infringing Products have taken, used, and orally administered the Infringing Products.
- 84. The Infringing Products were formulated, made, manufactured, shipped, distributed, advertised, market, offered for sale, and sold by Defendants to include certain ingredients that, by virtue of their inclusion in the Infringing Products, infringed one or more of the claims of the '446 Patent.
- 85. The Infringing Products were formulated, made, manufactured, shipped, distributed, advertised, marketed, offered for sale, and sold by Defendants to include certain ingredients that, by virtue of their inclusion in the Infringing Products, infringed one or more of the claims of the '446 Patent, and as a result when endusers of Defendants' Infringing Products orally administered the Infringing Products they were practicing the methods disclosed in one or more claims of that patent.
- 86. Defendants' labels and advertising for the Infringing Products explain and explained the elements and essential elements of one or more of the methods

disclosed in the '446 Patent, and those labels and advertising statements encouraged, urged, and induced, and continue to do so, the Infringing Products' end-users to purchase and orally ingest the products to practice those methods, and end-users did and continue to practice those methods.

- 87. Defendants therefore specifically intended to cause these end-users to directly infringe the claimed methods of the '446 Patent, and had and continue to urge them to do so.
- 88. The Infringing Products are not, and were not at any time, suitable for non-infringing uses, and none of Defendants' labels or advertisements for the Infringing Products disclosed any uses for the products, nor for the compounds disclosed in the claimed methods, that did not infringe upon such methods.
- 89. Defendants have and had knowledge that the Infringing Products were especially adapted by end-users of the products for the practicing of such methods, and indeed, Defendants encouraged, urged, and induced, and still encourage, urge and induce the Infringing Products' end-users to purchase and orally administer the Infringing Products and to practice the claimed methods.
- 90. Defendants intentionally and knowingly induced encouraged, urged, and induced, and still encourage, urge and induce the Infringing Products' end-users to purchase and orally administer the Infringing Products for the purpose of practicing

the claimed methods of the '446 Patent, by having them orally ingest the compounds disclosed in such claims.

- 91. Defendants had knowledge of the fact that the Infringing Products, particularly as administered, infringed on one or more claims of the '446 Patent.
- 92. Defendants had direct, firsthand knowledge of the '446 Patent itself.
- 93. Defendants' activities were without express or implied license by Plaintiff.
- 94. Defendants have profited though its infringement of the '446 patent, and continues to do so.
- 95. As a result of Defendants' acts of infringement, Plaintiff suffered, and will continue to suffer damages in an amount to be proved at trial.
- 96. Defendants intend to continue their acts of infringement, and Plaintiff has, and will continue to, suffer irreparable harm, for which there is no adequate remedy at law unless Defendants are enjoined by this Court from continuing such acts of infringement.
- 97. Defendants' past infringements and/or continuing infringements have been deliberate and willful, and this case is therefore an exceptional case, which warrants an award of treble damages and attorneys' fees in accordance with 35 U.S.C. §284 and § 285.

COUNT II Infringement Of U.S. Patent No. 8,338,399

98. Plaintiffs incorporate the foregoing paragraphs as if fully restated herein.

- 99. Defendants have, and continue to do so, literally and directly infringed, or directly infringed under the doctrine of equivalents one or more claims of United States Patent No. 8,338,399 by making, using, offering to sell, and/or selling in the United States, and/or importing into the United States the Infringing Products, or any one of those products.
- 100. In addition to the fact Defendants make, use, sell, and/or offer for sale the Infringing Products, and did so in the past, further examples of Defendants' direct infringements include, without limitation, the fact that Defendants encouraged and/or was aware that its employees, agents, representatives, and/or other persons sponsored by or who endorse Defendants and/or Defendants' Infringing Products in advertising and marketing activities, orally administered the Infringing Products, and practiced and continue to practice the methods disclosed in one or more claim of the '339 Patent, and these employees, agents, representatives, and/or other persons sponsored by or who endorse Defendants and/or Defendants' Infringing Products in advertising and marketing activities were acting under Defendants' direction and control when practicing these methods.
- 101. Defendants encouraged and were aware of these persons' oral administration of the Infringing Products for these purposes, these persons were acting under Defendants' direction and control, and therefore Defendants directly practiced the methods and/or claims of the '339 Patent.

- 102. End-users of Defendants' Infringing Products were also direct infringers of one or more claims of the '339 Patent.
- 103. End-users of Defendants' Infringing Products have taken, used, and orally administered the Infringing Products.
- 104. The Infringing Products were formulated, made, manufactured, shipped, distributed, advertised, market, offered for sale, and sold by Defendants to include certain ingredients that, by virtue of their inclusion in the Infringing Products, infringed one or more of the claims of the '339 Patent.
- 105. The Infringing Products were formulated, made, manufactured, shipped, distributed, advertised, marketed, offered for sale, and sold by Defendants to include certain ingredients that, by virtue of their inclusion in the Infringing Products, infringed one or more of the claims of the '339 Patent, and as a result when endusers of Defendants' Infringing Products orally administered the Infringing Products they were practicing the methods disclosed in one or more claims of that patent.
- 106. Defendants' labels and advertising for the Infringing Products explain and explained the elements and essential elements of one or more of the methods disclosed in the '339 Patent, and those labels and advertising statements encouraged, urged, and induced, and continue to do so, the Infringing Products' end-users to purchase and orally ingest the products to practice those methods, and end-users did and continue to practice those methods.

- 107. Defendants therefore specifically intended to cause these end-users to directly infringe the claimed methods of the '339 Patent, and had and continue to urge them to do so.
- 108. The Infringing Products are not, and were not at any time, suitable for non-infringing uses, and none of Defendants' labels or advertisements for the Infringing Products disclosed any uses for the products, nor for the compounds disclosed in the claimed methods, that did not infringe upon such methods.
- 109. Defendants have and had knowledge that the Infringing Products were especially adapted by end-users of the products for the practicing of such methods, and indeed, Defendants encouraged, urged, and induced, and still encourage, urge and induce the Infringing Products' end-users to purchase and orally administer the Infringing Products to practice such methods.
- 110. Defendants intentionally and knowingly induced, encouraged, urged, and induced, and still encourage, urge and induce the Infringing Products' end users to purchase and orally administer the Infringing Products for the purpose of practicing the claimed methods of the '339 Patent, by having them orally ingest the compounds disclosed in such claims.
- 111. Defendants had knowledge of the fact that the Infringing Products, particularly as administered, infringed on one or more claims of the '339 Patent.
- 112. Defendants had direct, firsthand know ledge of the '339 Patent itself.

- 113. Defendants' activities were without express or implied license by Plaintiff.
- 114. Defendants have profited though its infringement of the '339 patent, and continue to do so.
- 115. As a result of Defendants' acts of infringement, Plaintiffs suffered, and will continue to suffer damages in an amount to be proved at trial.
- 116. Defendants intend to continue their acts of infringement, and Plaintiffs have, and will continue to, suffer irreparable harm, for which there is no adequate remedy at law unless Defendants are enjoined by this Court from continuing such acts of infringement.
- 117. Defendants' past infringements and/or continuing infringements have been deliberate and willful, and this case is therefore an exceptional case, which warrants an award of treble damages and attorneys' fees in accordance with 35 U.S.C. § 284 and § 285.

COUNT III FALSE ADVERTISING IN VIOLATION OF SECTION 43(A)(1)(B) OF THE LANHAM ACT

- 118. Plaintiffs hereby incorporate the allegations contained in the foregoing paragraphs as though fully set forth herein in their entirety.
- 119. Defendants have purposely made false and misleading descriptions of fact concerning the nature, characteristics and qualities of its "nutritional supplements" DMZ 4.0^{TM} and Osta Rx^{TM} , by failing to tell the consumers that these products

- contain (2S)-3-(4-cyanophenoxy) -N- [4-cyano-3- (trifluoromethyl)phenyl] -2 hydroxy -2- methylpropanamide) which is an unapproved new drug and is untested on humans and potentially dangerous.
- 120. Defendants' marketing of such misbranded and falsely-labeled substances has the tendency to deceive a substantial segment of the public into believing that they are purchasing a product with different characteristics. By failing to list this potentially harmful ingredient on their label, Defendants have misled consumers.
- 121. The deception is material because it is likely to influence a consumer's purchasing decision, especially if the consumer has concerns about the consequences of ingesting an untested product or one considered an unapproved new drug by FDA without proper expert oversight.
- 122. Defendants have introduced their false statements into interstate commerce via marketing and advertising on various websites and shipment of its product into interstate commerce containing false labeling.
- 123. Defendants' actions, as described above, constitute false and misleading descriptions and misrepresentations of fact in commerce which, in commercial advertising and promotion, misrepresent the nature, characteristics, and qualities of its products in violation of Section 43(a)(1)(B) of the Lanham Act.
- 124. Hi-Tech's body building products have natural ingredients and compete directly with Defendants' Super DMZ 4.0TM and Osta RxTM products.

125. As a result of Defendants misrepresentations, Hi-Tech has suffered both an ascertainable economic loss of money and reputational injury by the diversion of business from Hi-Tech to Defendants and the loss of goodwill in Hi-Tech's products. Indeed, Defendants' conduct is a black eye on the industry as a whole, and has the tendency to disparage and diminish Hi-Tech's products and goodwill.

COUNT IV

VIOLATION OF THE GEORGIA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT, O.C.G.A. §10-1-372 (a)

- 126. Plaintiffs incorporate the foregoing paragraphs as if fully restated herein.
- 127. Hi-Tech and Defendants are commercial competitors. Defendants' actions as described above constitute deceptive and unfair trade practices in violation of O.C.G.A. §10-1-372 (a).
- 128. The Georgia Deceptive and Unfair Trade Practices Act was enacted to protect the public and legitimate business enterprises from those who engage in unfair methods of competition and unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce.
- 129. Defendants' actions, as alleged herein, constitute unconscionable commercial practices, deception, fraud, false pretense, false promise, and/or misrepresentation in violation of O.C.G.A. §10-1-372 (a).
- 130. Upon information and belief, consumers reasonably and justifiably relied on Defendants' deceptive, unfair, and fraudulent misrepresentations as alleged herein.

Consumers were certain to be deceived because Defendants' knowingly failed to disclose the source, affiliation, origin, characteristics, ingredients, standards and/or quality of its Infringing Products. Defendants' business practices, in the advertising, marketing, packaging, labeling, and sale of its Infringing Products as a unique and superior product, justify selection of the product over alternative dietary supplements.

- 131. As a direct and proximate result of Defendants' unlawful acts and omissions, Hi-Tech has suffered an ascertainable loss of money or property in the form of diverted or lost sales.
- 132. Hi-Tech is without remedy at law and Defendants' deceptive trade practices as set forth herein continue, and will continue, unless enjoined by this Court.
- 133. Plaintiffs are therefore entitled to compensatory and punitive damages, equitable and injunctive relief, costs, and reasonable attorney fees.

COUNT V COMMON LAW UNFAIR COMPETITION AGAINST DEFENDANTS

- 134. Plaintiffs incorporate the foregoing paragraphs as if fully restated herein.
- 135. Defendants' actions, as set forth above, constitute unfair competition in violation of the common law of the State of Georgia.
- 136. Defendants' actions as described herein have caused and will continue to cause irreparable injury to Hi-Tech and, unless restrained, will continue to do so.

- 137. As a direct and proximate result of Defendants' conduct, Hi-Tech has suffered damages in an amount to be determined at trial.
- 138. Defendants' actions entitle Hi-Tech to compensatory damages in an amount to be determined at trial and punitive damages under the common law.
- 139. Defendants' actions are such as to constitute that level of wantonness and lack of care to justify punitive damages under Georgia law.
- 140. Hi-Tech is without remedy at law and Defendants' deceptive trade practices as set forth herein continue, and will continue, unless enjoined by this Court.
- 141. Plaintiffs are therefore entitled to compensatory damages, punitive damages, equitable and injunctive relief, costs, and reasonable attorney fees

COUNT VI

CONSPIRACY TO VIOLATE THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1962(c)(d)

- 142. Plaintiffs incorporate the foregoing paragraphs as if fully restated herein.
- 143. Upon information and belief, Mr. Dimaggio operated and managed the affairs of IronMag Labs throughout all relevant times.
- 144. IronMag Labs and Mr. Dimaggio knowingly engaged in a scheme to intentionally defraud Hi-Tech out of sales and profits though IronMag Labs' infringement of Hi-Tech's patents and sales on their Super DMZ 4.0^{TM} and Osta Rx^{TM} products.

- 145. In intentional furtherance of this scheme, IronMag Labs used the Internet to disseminate IronMag Labs' Infringing Products and illegal Super DMZ 4.0^{TM} and Osta Rx^{TM} to consumers across the United States, and to enable consumers to purchase IronMag Labs' Infringing Products and illegal Super DMZ 4.0^{TM} and Osta Rx^{TM} online.
- 146. In intentional furtherance of this scheme, IronMag Labs also used the U.S. Mail and/or other interstate carriers to ship its Infringing Products and illegal Super DMZ 4.0TM and Osta RxTM, to purchasing consumers throughout the United States. 147. Defendant Dimaggio agreed with others associated with and employed by IronMag Labs to participate in and facilitate the fraudulent scheme set forth herein and had actual knowledge of IronMag Labs' fraudulent activities set forth herein. 148. Defendants' infringement upon Hi-Tech's patents in suit and fraudulent activities described herein deceived consumers into believing IronMag Labs' products were lawful, and caused and enabled consumers to purchase IronMag Labs'
- 149. IronMag Labs and Mr. Dimaggio also knowingly engaged in a scheme to intentionally defraud Hi-Tech out of sales and profits though IronMag Labs' false product claims regarding Super DMZ 4.0TM and Osta RxTM content, quality, characteristics, and/or ingredients.

products instead of Hi-Tech's products.

- 150. In intentional furtherance of this scheme, IronMag Labs used the Internet to disseminate its false product claims to consumers across the United States, and to enable consumers to purchase IronMag Labs' Super DMZ 4.0TM and Osta RxTM products online.
- 151. In intentional furtherance of this scheme, IronMag Labs also used the U.S. Mail and/or other interstate carriers to ship Super DMZ 4.0TM and Osta RxTM, the subject of the false product claims, to consumers throughout the United States.
- 152. Upon information and belief, IronMag Labs engaged in the fraudulent activities set forth above on a repeated and continuous basis over the course of, at least, the past three (3) years. IronMag Labs continues to engage in said fraudulent activities to date.
- 153. As set forth herein, Defendants agreed and conspired to violate 18 U.S.C. § 1962(c). Specifically, Defendants conspired to conduct the affairs of IronMag Labs, the enterprise, through a pattern of racketeering activity as part of their scheme to engage in false advertising regarding the IronMag Labs's Super DMZ 4.0TM and Osta RxTM product, defrauding Hi-Tech of sales and profits.
- 154. In furtherance of this scheme to engage in false advertising, Defendants agreed to, and did, use the internet to disseminate its false product claims to consumers across the United States, and used the Internet to enable consumers to

purchase IronMag Labs's Super DMZ 4.0TM and Osta RxTM product online in violation of 18 U.S.C. § 1343.

- 155. Also in furtherance of this scheme to engage in false advertising, Defendants agreed to, and did, use the U.S. Mail and/or other interstate carriers to ship Super DMZ 4.0TM and Osta RxTM, the subject of the false product claims, to consumers throughout the United States in violation of 18 U.S.C. § 1341.
- 156. As set forth herein, Defendants agreed and conspired to violate 18 U.S.C. § 1962(c). Specifically, Defendants conspired to conduct the affairs of IronMag Labs, the enterprise, through a pattern of racketeering activity as part of their scheme to unlawfully defraud consumers and Hi-Tech and to infringe upon Hi-Tech's patents in suit.
- 157. In furtherance of this scheme to unlawfully infringe upon Hi-Tech's NitroPro® trademark, Defendants agreed to, and did, use the internet to disseminate its IronMag Labs's infringing Super DMZ 4.0TM and Osta RxTM mark to consumers across the United States, and used the Internet to enable consumers to purchase IronMag Labs's Super DMZ 4.0TM and Osta RxTM product online in violation of 18 U.S.C. § 1343.

 158. Defendants have intentionally conspired to conduct and participate in the conduct of the affairs of the enterprise through a pattern of racketeering activity. Defendants knew that their predicate acts were part of a pattern of racketeering activity and agreed to the commission of those acts to further the schemes described

above. That conduct constitutes conspiracy to violate 18 U.S.C. § 1962(c), in violation of 18 U.S.C. § 1962(d).

159. As a direct and proximate result of Defendants' conspiracy, the overt acts taken in furtherance of that conspiracy, and violations of 18 U.S.C. § 1962(d), Plaintiff has been injured in its business and property by lost or diverted sales and by injury to its business, the reputation and goodwill of its branded products, and its ability to compete in the marketplace. As a result of the Defendants' violations of 18 U.S.C. § 1962(d), Plaintiffs are entitled to actual damages, treble damages, costs, and attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

- 1. That Hi-Tech and Intellectual Wellness be awarded a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure;
- 2. For a declaration that Defendants has infringed the Patents in Suit and/or induced others to infringe one or more claims of the Patent in Suit, in violation of 35 U.S.C. §§271 *et seq.*;
- 3. For a declaration that Defendants' infringement and/or inducement to infringe the Patents in Suit has been willful and deliberate;

- 4. That Defendants be required to provide Plaintiffs an accounting of all sales, gains, profits, and advantages derived by Defendants' infringements of the Patents in Suit.
- 5. That Plaintiffs be awarded compensatory damages, together with interest and costs, adequate to compensate Plaintiff for the wrongful infringing acts by Defendants in accordance with 35 U.S.C. §284;
- 6. That Plaintiffs be awarded treble damages and pre-judgment interest under 35 U.S.C. § 284 with regard to the Patent in Suit in light of Defendants' willful and deliberate infringement, in accordance with 35 U.S.C. §284;
- 7. That this case be declared exceptional in favor of Plaintiffs under 35 U.S.C. § 285 and that Plaintiff be awarded its reasonable attorneys' fees and other expenses incurred in connection with this action pursuant to 35 U.S.C. §§ 284 and 285 and Rule 54(d) of the Federal Rules of Civil Procedure.
- 8. That IronMag Labs be adjudged to have violated 15 U.S.C. §1125(a) by unfairly competing against Hi-Tech by using false, deceptive or misleading statements of fact that misrepresent the nature, quality, and characteristics of the IronMag Labs products.
- 9. That Mr. Dimaggio be adjudged to have violated 15 U.S.C. §1125(a) by unfairly competing against Hi-Tech by using false, deceptive or misleading

statements of fact that misrepresent the nature, quality, and characteristics of the IronMag Labs products.

- 10. That such damages and profits be trebled and awarded to Hi-Tech as a result of Defendants' willful, intentional and deliberate acts in violation of the Lanham Act.
- 11. That Hi-Tech recover actual damages, treble damages, costs, and attorney fees for Defendants' violation of 18 U.S.C. § 1962(c)(d).
- 12. That all of Defendants misleading and deceptive materials and products be destroyed as permitted under 15 U.S.C. § 1118.
- 13. That Defendants be adjudged to have unlawfully and unfairly competed against Hi-Tech under the laws of the State of Georgia, §10-1-372 (a).
- 14. For an order granting both preliminary and permanent injunctions pursuant to 35 U.S.C. §283, enjoining the Defendants from further acts of infringement;
- 15. That Plaintiffs be awarded Punitive Damages pursuant to both Georgia and federal law; and
- 16. That Plaintiffs be awarded such other relief as this Court may deem just and proper.

This 6th day of November, 2015.

S/ Edmund J. Novotny
Edmund J. Novotny, Jr.
Georgia Bar No. 547338
Charles R. Bridgers
Georgia Bar No. 080791
Attorneys for Hi-Tech
Pharmaceuticals, Inc.

101 Marietta Street Suite 3100 Atlanta, Georgia 30303 Tel: 404-979-3150

Fax: 404-979-3170

ednovotny@novotnylawgroup.com

S/ John T. Gallagher
John T. Gallagher
Attorney for Hi-Tech
Pharmaceuticals, Inc.

Hoffmann & Baron, LLP 6900 Jericho Turnpike Syosset, New York 11791 Telephone: (516) 822-3550 Direct Dial: (516) 608-4728 Facsimile: (516) 822-3582

jgallagher@hbiplaw.com