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

HI-TECH PHARMACEUTICALS	)	
INC.,	)	
	)	
Plaintiff,	)	
	)	
V.	)	CIVIL ACTION NO.:
	)	
PIETER A. COHEN,	)	
CLAYTON BLOSZIES,	)	
CALEB YEE and ROY GERONA	)	
	)	
Defendants.	)	

# **Complaint**

COMES NOW, the Plaintiff, Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech"), by and through the undersigned counsel of record, and for its Complaint against the Defendants, states as follows:

# I. <u>Parties</u>

1. Hi-Tech is 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 does substantial business within the State of Georgia, and throughout the United States, including manufacturing, sales, distribution, marketing and promotion of dietary supplement products, including products containing Acacia Rigidula, and Hi-Tech enjoys an international reputation

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for excellence in the dietary supplement industry. Hi-Tech has earned and maintained brand recognition, goodwill, and a positive reputation in the community of dietary supplements consumers, suppliers and retailers.

2. Defendant Pieter A. Cohen ("Cohen"), is an individual and general internist at the Cambridge Health Alliance and assistant professor of medicine at Harvard Medical School. Pieter A. Cohen may be served with process at 236 Highland Avenue, Somerville, Massachusetts 02143.

3. Defendant Clayton Bloszies ("Bloszies"), is an individual and works at the Department of Chemistry at Haverford College. Clayton Bloszies may be served with process at 370 Lancaster Avenue Haverford, Pennsylvania 19041.

4. Defendant, Caleb Yee ("Yee"), is an individual and works at the Department of Laboratory Medicine, University of California, San Francisco. Caleb Yee may be served with process at 513 Parnassus Ave, Med Science Department of Laboratory Medicine San Francisco CA 94143.

5. Defendant Roy Gerona ("Gerona"), is an individual and works at the Department of Laboratory Medicine, University of California, San Francisco. Roy Gerona may be served with process at 513 Parnassus Ave, Med Science Department of Laboratory Medicine San Francisco CA 94143.

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### II. Jurisdiction and Venue

6. This is an action for injunctive relief, compensatory and punitive damages against Defendants Cohen, Bloszies, Yee, and Gerona who have violated Georgia's Uniform Unfair Trade Practices Act and published false and malicious statements about the safety and efficacy of dietary supplements containing Acacia Rigidula manufactured by Hi-Tech and others, with the intent to influence the Food and Drug Administration ("FDA") and cause damage to Hi-Tech's business and its present and future business relations.

7. This court has original jurisdiction based upon Georgia's Long Arm Statute, O.C.G.A.§ 9-10-91(2), as well as the substantial-federal-question jurisdiction doctrine set forth in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308, 125 S. Ct. 2363, 162 L. Ed. 2d 257 (2005) and its progeny.

8. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391 because Plaintiff's principal place of business is located in the Northern District of Georgia and many of the damages that are the subject of this Complaint occurred in this District.

9. Pursuant to 28 U.S.C. § 1367, this Court also has supplemental jurisdiction over Hi-Tech's claims arising from the laws of the State of Georgia as those claims

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are substantially related to those causes of action over which the Court has original jurisdiction.

10. Jurisdiction is also conferred on this Court pursuant to 28 U.S.C. § 1332(a)(1) through diversity of citizenship, as the 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). Plaintiff is a corporation of the State of Georgia for purposes of diversity jurisdiction under 28 U.S.C. § 1332. Defendant Cohen is a citizen of Massachusetts. Defendant(s) Yee and Gerona are citizens of California; and Defendant Bloszies is a citizen of Pennsylvania.

### **III.** Summary of the Case

11. Defendants Cohen, Bloszies, Yee, and Gerona have published and/or uttered multiple false and malicious statements about the safety of dietary supplements containing Acacia rigidula manufactured by Hi-Tech and others, with the intent to incite enforcement action against Hi-Tech from the FDA and to defame and disparage Hi-Tech's products and commercial reputation.

12. The false statements published by Defendants conveyed to the average listener or reader, and the FDA the overall net impression that Plaintiff illegally manufactures and sells products with a synthetic amphetamine isomer known as  $\beta$ -methylphenylethylamine (BMPEA) while falsely labeling the ingredient as Acacia rigidula.

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13. Thus, Defendants published false information that Plaintiff is selling adulterated, dangerous and illegal products and is engaged in criminal activity which the Defendants contend the FDA refused to enforce or properly regulate.

14. As a result of Defendants' false information, the FDA issued a Warning Letter from the FDA on or about April 22, 2015 requiring that Plaintiff cease using Acacia rigidula in its products.

15. In an effort to pursue their crusade against dietary supplements and to wrongfully influence the FDA, Defendants ignored fundamental canons and methods of scientific investigation and integrity and published accusations which Defendants knew or should have known were false.

### IV. Statement of the Facts

# A. Plaintiff Hi-Tech Pharmaceuticals, Inc., and its Products Containing Acacia rigidula.

16. Acacia rigidula is a species of shrub or small tree in the legume family, *Fabaceae*. Its native range stretches from Texas in the United States south to central Mexico. The plant has been used in traditional medicine by Native Americans for many years to treat a variety of ailments. Acacia rigidula contains about 40 different chemical compounds and amines and has become famous for its promotion of weight loss and energy and its ability to elevate mood and metabolic rate. Among the many compounds is naturally occurring beta-methylphenylethylamine (BMPEA), which is a phenylethylamine alkaloid,

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17. Plaintiff Hi-Tech developed an extract of Acacia rigidula in late 2003, in conjunction with its overseas raw material manufacturer. Hi-Tech expended vast resources to bring its Acacia extract to market and derives a substantial portion of its revenues through the sale of its branded products containing the ingredient as well as its sales through contract manufacturing and providing Acacia rigidula as a raw material.

18. Hi-Tech's Acacia rigidula extract was standardized to contain many of the active alkaloids found by Texas A&M researchers in 1997 and 1998 while researching the Acacia species. Texas A&M enjoys a particularly strong reputation for excellence in the area of research and development related to Department of Veterinary Integrative Biosciences and Department of Agricultural and Life Sciences. The Acacia rigidula extract used in Hi-Tech products employs a proprietary extraction technology developed by a leading Chinese botanical factory and based, in part, on the research conducted at Texas A&M.

19. The Acacia rigidula extract used by Hi-Tech has been continually lab-tested by several certified testing facilities and has been continually used and accepted for import by the FDA and U.S. Customs for use in dietary supplements since approximately 2004. The Acacia rigidula extract has been deemed safe enough to conduct human trials by several Internal Review Boards.

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20. Among the well-known Hi-Tech products containing Acacia rigidula are Fastin XR<sup>TM</sup>, Fastin Rapid Release<sup>TM</sup>, Lipodrene<sup>TM</sup>, Stimerex ES<sup>TM</sup>, and Black Widow<sup>TM</sup>, among others.

21. Hi-Tech has also invested large sums of money on double-blind, placebocontrolled clinical trials of its products to ensure their safety and efficacy. See http://www.prnewswire.com/news-releases/hi-tech-pharmaceuticals-announcesfastin-rapid-release-clinical-study-results-300058770.html

22. Despite having sold many millions of doses of dietary supplement products containing Acacia rigidula since 2004, Hi-Tech is unaware of any report of serious illness, injury, or death from any consumer of its Acacia rigidula products.

### **B.** Defendants' Crusade Against Dietary Supplements.

23. On October 25 1994, then President Bill Clinton signed the *Dietary Supplement Health and Education Act* (DSHEA) into law, saying that "After several years of intense efforts, manufacturers, experts in nutrition, and legislators, acting in a conscientious alliance with consumers at the grassroots level, have moved successfully to bring common sense to the treatment of dietary supplements under regulation and law." See http://www.health.gov/dietsupp/execsum.htm

24. One of the primary reasons Congress enacted the DSHEA was because of the FDA's historic heavy-handed regulation and enforcement of supplements had led to the FDA's treatment of supplements to be more like pharmaceuticals than foods,

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thus restricting consumer access to supplements and making them unnecessarily expensive.

25. Defendants have publicly stated on many occasions their belief that dietary supplements are now inadequately regulated and that they should be subject to premarket testing and regulated by the FDA like a pharmaceutical drug; *i.e.*, the same policy rejected by the public and U.S. Congress when DSHEA was enacted.

26. Over the past several years, Defendants have engaged in a public effort to promote their agenda through the media by publishing articles on their research and then granting interviews wherein they make outrageous claims regarding the results and implications of their research and regularly attack the FDA as being lax in its enforcement responsibilities.

27. Defendant Cohen has appeared on national television shows, in interviews, and has written extensively about his beliefs that supplements are dangerous and that the FDA fails to adequately enforce DSHEA's labeling and manufacturing rules.

28. Defendant Cohen's crusade can be seen in the titles of many of his publications such as:

- Cohen PJ. Science, politics and the regulation of dietary supplements: it's time to repeal DSHEA. Am J Law Med2005;31:175-214
- Cohen PA. American roulette--contaminated dietary supplements. N Engl J Med. 2009 Oct 15; 361(16):1523-5.
- Cohen PA. *Hazards of hindsight--monitoring the safety of nutritional supplements*. N Engl J Med. 2014 Apr 3; 370(14):1277-80.
- Cohen PA. The natural pill myth. The Boston Globe. 2012; May 13

- Cohen PA. A false sense of security? The U.S. Food and Drug Administration's framework for evaluating new supplement ingredients. Antioxid Redox Signal. 2012 Mar 1; 16(5):458-60
- Cohen, PA. *How America's Flawed Supplement Law Creates the Mirage of Weight Loss Cures*. Harvard Public Health Review. 2014; 2(1).
- Cohen PA. Assessing supplement safety--the FDA's controversial proposal. N Engl J Med. 2012 Feb 2; 366(5):389-91.
- Cohen PA, Rasmussen N. *A nation of kids on speed*. Wall Street Journal. 2013; June 17.
- Cohen PA, Edgar E. *Keep unsafe energy drinks off bases*. Stars and Stripes. 2013; March 4.

29. As shown below, Defendant Cohen's subjective personal and political agenda has led him, his colleagues, and the FDA to abandon scientific objectivity when evaluating Acacia rigidula.

# C. Defendants' Attack on Acacia Rigidula and Plaintiff's Products.

30. On or about April 7 2014, Defendants caused to be published in a journal known as "*Drug Testing and Analysis*"<sup>1</sup> an article entitled, "An amphetamine isomer whose efficacy and safety in humans has never been studied,  $\beta$ -methylphenylethylamine (BMPEA), is found in multiple dietary supplements," which included a listing of Hi-Tech products purportedly tested by the Defendants.

31. The article contained allegations that when viewed by an average reader would leave the impression that, among other things, Plaintiff's products containing

<sup>&</sup>lt;sup>1</sup> The journal's articles typically focus on, among other things, sports doping and illicit/recreational drug use.

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Acacia rigidula are knowingly adulterated, misbranded, mislabeled, and dangerous to consumers.

32. Upon information and belief, one or more of the Defendants promoted and disseminated, or caused to be disseminated, the journal article and/or a press release regarding the aforementioned article to various broadcast, print, and internet news outlets.

33. As a result, Defendants were granted interviews wherein they provided further defamatory comments and statements critical of the FDA. Such further defamatory comments were subsequently broadcast or disseminated in over 200 interviews or news articles including, but not limited to:

- A. An April 7, 2015 video interview with CBS This Morning
- B. An online article by CBS at http://www.cbsnews.com/news/newstudy-warns-against-dietary-supplements-containing-bmpea-callsfda-action/
- C. An online article by USA today at http://www.usatoday.com/ news/2015/04/07/weight-loss-supplements-amphetaminessports/25380525/
- D. An April 23, 2015 New York Times article at: http://well.blogs.nytimes.com/2015/04/23/f-d-a-warns-supplementmakers-of-bmpea-stimulant-dangers/?\_r=0

See Exhibit A for a listing of internet sites containing interviews or report of the publication and Defendants' comments.

34. In the news articles and interviews Defendants falsely accuse Plaintiff of selling products that are illegal and/or dangerous. Defendant Cohen was quoted as

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saying "BMPEA has not been tested in humans, but led to increased blood pressure in cats and dogs. These are things that are signals that in humans will later turn into heart attacks, strokes and maybe even sudden death."

35. In the news articles and interviews Defendant Cohen also falsely states, "We took a look at a new replacement for ephedra the name for this is Acacia rigidula, but in fact, it does not have that plant in it at all. It has new, designer stimulant called BMPEA".

36. This statement convey a grossly inaccurate and false impression that Acacia rigidula is not in Plaintiff's products and it instead uses an illegal synthetic substance in its place.

37. In the news articles and interviews Defendant Cohen also states FDA "completely dropped the ball" in its responsibility to prevent the inclusion of dangerous ingredients in supplements. This statement shows Defendant Cohen's motive to incite FDA enforcement and is defamatory per se in that it implicitly accused Plaintiff of adulterating its products.

38. In the news articles and interviews Defendant Cohen also states "The FDA not only has to move against BMPEA, but they need to move against this product to set an example of what are they going to do when other companies are introducing new stimulants," which again show Defendant Cohen's motive to incite FDA

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enforcement and again infers to readers and listeners that Plaintiff's products are illegal.

39. Defendant Cohen's motives are again evident when he stated "This is really about the FDA and why the FDA is not enforcing the law," in an interview with NutraIngredientsUSA. "This is a great example of how the FDA could so easily move now and . . . not wait until strokes and heart attacks become front page news." 40. In the news articles and interviews Defendant Cohen also states "One, is that the supplement's not going to work and you're just wasting your money, and the other option is that it's actually working, leading to short-term weight loss, but exposing you to serious long-term risks,", which when read in context conveys a false and defamatory impression that Plaintiff's products are ineffective and/or unsafe.

41. In the news articles and interviews Defendant Cohen also quotes the FDA saying: "While our review of the available information on products containing BMPEA does not identify a specific safety concern at this time" and Defendant Cohen in response stated "I was shocked when I saw this." He further stated in other interviews "Let's not wait until we have a body count," he said. "Just get the job done." These statements are false and defamatory per se in that the imply Plaintiff's products may cause death if the FDA does not take any regulatory action.

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42. In the articles and interviews Defendant Cohen also states "There is not a single weight loss supplement on the market that is legal and that has been shown to lead to weight loss in humans," which implies that Plaintiff's products are not legal and/or not efficacious.

43. Defendant Cohen claims to be an expert on weight loss and, therefore, knows or should know of a plethora of scientific studies on dietary supplements and their ingredients that have demonstrated their efficaciousness in promoting weight loss.

44. In the news articles and interviews Defendant Cohen also states "The scary thing is that we have absolutely no idea ... We know it is structurally almost identical to speed and in animals it has similar effects. In humans, we have no idea, but similar types of compounds have been linked to strokes and sudden death."

45. In the news articles and interviews Defendant Cohen also states "'Acacia rigidula' is code in the industry for a potent synthetic stimulant... They are using the name as a cover." Defendant's statement implies that Plaintiff's products do not, in fact, contain Acacia rigidula which is patently untrue.

46. Defendants' published journal article states "Check your shelf for any supplements with the words 'Acacia rigidula'" and that this is "the red-flag ingredient and another name for beta-methylphenylethylamine (BMPEA)," which would lead the reader to imply that Acacia rigidula is not a lawful ingredient and

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that Hi-Tech's products containing Acacia rigidula do not in fact contain a natural ingredient but rather synthetic BMPEA.

47. In the news articles and interviews Defendant Cohen also states "I don't think we should be sitting around waiting for someone to die before we take something off of the market that shouldn't have been there in the first place." This statement is false and defamatory per se in that it implies Plaintiff's products are dangerous and capable of killing someone if FDA does not take any regulatory action and that Acacia rigidula is not a dietary supplement that is legal.

48. In the news articles and interviews Defendant Cohen also states, "Some manufacturers of weight-loss supplements do list BMPEA on the label, but they imply that it comes from Acacia rigidula extract. However, there is no evidence that this is true." Defendant Cohen knows or should have known from a review of the existing scientific literature that naturally occurring BMPEA is found in Acacia rigidula.

49. Defendant Cohen was asked in an interview about a statement released by Hi-Tech and provided to CBS News, that "Hi-Tech has sold over 1 billion doses since 2003 of Acacia rigidula and its alkaloids and have conducted numerous studies of these alkaloids and believe them to be safe and effective when used as directed. "Defendant Cohen disagreed and falsely stated. "FDA's data suggests that the natural compounds found in Acacia rigidula are not present in these supplements regardless

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of the presence of BMPEA." Moreover, "BMPEA has never been found in Acacia rigidula or any other plant."

50. In the news articles and interviews Defendant Cohen also states "BMPEA, which was presumably added to the Acacia rigidula products, has never been proved safe for human use" and that "BMPEA is in a sense, being tested on buyers," Cohen says. "The consumer becomes the guinea pig." Defendant Cohen's statements are false and imply that Plaintiff's products substitute synthetic BMPEA for Acacia rigidula and that Plaintiff's products are unsafe and have not been tested for safety.

51. In the articles and interviews Defendant Cohen also states, "This is a brand new drug being placed into a number of supplements under the guise of a natural ingredient." Defendant Cohen's statement is false and defamatory in that it implies that Plaintiff's products are misbranded and illegal because they contain a synthetic drug.

52. In the news articles and interviews Defendant Cohen also states "Consumers should be warned to shun all supplements labeled as containing Acacia rigidula. Doctors should remain vigilant to the possibility that patients might be inadvertently exposed to synthetic stimulants when consuming weight-loss and sports supplements." Defendant Cohen's statements are false and defamatory in that they imply that Plaintiff's products contain synthetic stimulants.

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53. Because Defendants did not review the existing scientific literature and did not conduct their testing with reliable scientific protocols, their testing for BMPEA in Plaintiff's products does not form a reliable basis for their allegations of adulteration or contamination.

54. Defendants apparently did not do basic or sufficient research on Acacia rigidula or Hi-Tech's products before publishing their accusations because their statements were easily verifiable as false. A cursory view on the internet would have found three (3) double-blind, placebo controlled clinical studies on supplements containing Acacia rigidula performed on humans by Hi-Tech and five (5) clinical studies performed on VPX's weight loss product Meltdown that included BMPEA in its labeling.

55. Defendants apparently did not do any due diligence to confirm the 2013 FDA test results on Acacia rigidula to see if they were consistent with what the scientific community had previously reported on naturally occurring BMPEA being found in various Acacia species. For (60) years and in dozens of studies BMPE, a phenylethylamine alkaloid, has been reported as a naturally occurring compound found in Acacia plants. Defendants are not organic chemists or scientists specializing in botanical products. Defendants have no specialized expertise or training in alkaloids or botanical extracts and the effects of soil conditions, stability of alkaloids,

and other similar expertise in such fields to render the conclusions they did in their journal article or subsequent interviews.

56. For example, had Defendants undertaken basic research they would have discovered the following studies which demonstrate that BMPEA is not a synthetic compound but appears naturally in Acacia species:

- Adams, Herman R. & Bennie J. Camp (1966) *Toxicon*, 4: 85–90. "The Isolation and Identification of Three Alkaloids from *Acacia berlandieri*."
- Camp, Bennie J. (1956) *PhD dissertation, Texas A&M University,* "The alkaloid of *Acacia berlandieri*, -Methyl-β-phenylethylamine."
- Camp, Bennie J. (1970) *American Journal of Veterinary Research*, 31 (4): 755–762, "Action of N-methyltyramine and N-methyl-beta-phenylethylamine on certain biological systems."
- Camp, Bennie J. & Carl M. Lyman (1956) *Journal of the American Pharmaceutical Association, Scientific Edition*, 45 (11): 719–721. "The Isolation of N-Methyl beta-Phenethylamine from *Acacia berlandieri*."
- Camp, Bennie J. & Carl M. Lyman (1957) *The Southwestern Veterinarian*, 10: 133–134. "The toxic agent isolated from *Acacia berlandieri*, N-methyl beta-phenylethylamine."

# COUNT I: VIOLATIONS OF THE UNIFORM DECEPTIVE TRADE PRACTICES ACT

57. Plaintiff Hi-Tech re-alleges and incorporates by reference herein Paragraphs1 through 56 above.

58. Defendants' public communications set forth above represented that Plaintiff's products have characteristics and ingredients that they do not have.

59. Defendants' public communications set forth above misrepresented that Plaintiff's products were of a quality and standard that would leave the average consumer to believe they are adulterated, misbranded, and mislabeled

60. Defendants' public communications set forth above disparaged Plaintiff's products by false and misleading representations of fact.

61. Defendants' conduct therefore violates the Uniform Deceptive Trade Practices Act, O.C.G.A. § 10-1-372 *et seq.* in that Defendants have disparaged Plaintiff and its products.

62. As a direct and proximate result of Defendants' violation of O.C.G.A. § 10-1-372 *et seq.*, Plaintiff received a warning letter from the FDA on or about April 22, 2015 requiring that Plaintiff cease using Acacia rigidula in its products. Plaintiff has also lost substantial sales, lost goodwill from its vendors, customers, contractors, the general public, and a diminishment of its reputation.

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63. Plaintiff is therefore entitled to injunctive relief as provided by the Uniform Deceptive Trade Practices Act, O.C.G.A. § 10-1-372 *et seq.* 

# **COUNT II: LIBEL**

64. Plaintiff Hi-Tech re-alleges and incorporates by reference herein Paragraphs1 through 63 above.

65. Defendants published the false and defamatory accusations against Plaintiff as set forth above.

66. Defendants published the false and defamatory accusations against Plaintiff as set forth above without any statutory, common law, or constitutional privilege.

67. The false and defamatory accusations against Plaintiff published by Defendants were subsequently republished worldwide and on numerous Internet websites.

68. Defendants' journal article and subsequent interviews and communications contain the following false or misleading statements (including purported lab tests and photographs) regarding Plaintiff's Acacia rigidula products containing b-methylphenylethylamine:

- (a) That the amphetamine isomer b-methylphenylethylamine (BMPEA) was first synthesized in the early 1930's, but its efficacy and safety in humans has not been studied;
- (b) That Acacia rigidula is "a new replacement for ephedra . . .but in fact, it does not have that plant in it at all. It has new, designer stimulant called BMPEA";

- (c) That supplement products containing Acacia rigidula are potentially deadly. "Let's not wait until we have a body count," he said. "Just get the job done";
- (d) That BMPEA remained known only as a research chemical until early 2013;
- (e) That BMPEA has never been identified or extracted from Acacia rigidula, a shrub native to Southwestern United States and Mexico;
- (f) That FDA should immediately warn consumers about BMPEA and take aggressive enforcement action to eliminate BMPEA in dietary supplements;
- (g) That the efficacy and safety of BMPEA has never been studied in humans; therefore, BMPEA's effect on human health is entirely unknown;
- (h) That BMPEA has not been sold as a food or supplement and, therefore, is not a legitimate supplement ingredient;
- (i) That consumers should be advised to avoid all supplements labeled as containing Acacia rigidula;
- (j) That "Acacia rigidula is code in the industry for a potent synthetic stimulant,..." "They are using the name as a cover ";
- (k) That "BMPEA has never been found in Acacia rigidula or any other plant";
- (1) That "[t]his is a brand new drug being placed into a number of supplements under the guise of a natural ingredient";
- (m) That "BMPEA is in a sense, being tested on buyers,..." "The consumer becomes the guinea pig"; and
- (n) That "we should [not] be sitting around waiting for someone to die before we take something off of the market that shouldn't have been there in the first place."

69. The communications of Defendants as set forth above constitute libel in violation of O.C.G.A. § 51-5-1 *et seq*.

70. The communications of Defendants as set forth above constitute libel per se in that they impute criminal activity to Plaintiff.

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71. The communications of Defendants as set forth above constitute libel per se in that they impute actions to Plaintiff that injure its business reputation.

72. The communications of Defendants as set forth above constitute libel per se in that they impute actions to Plaintiff that are defamatory and injurious to its reputation on their face and can be so understood without reference to any additional or extrinsic facts.

73. Defendants' false and defamatory statements set forth above have caused and will continue to cause damage to Hi-Tech's consumer sales, brands, sales in the raw material and contract manufacturing divisions and loss of reputation and goodwill with regulatory authorities, vendors, business partners and customers.

74. Defendants' false and defamatory statements set forth above are the direct and proximate cause of the damages alleged above.

75. At least ten (10) days prior to the filing of this action, Defendants were informed that their communications regarding the subject matter herein were false and defamatory and were requested to retract their statements. Evidencing a reckless disregard for truth or falsity, Defendants intentionally disregarded and ignored the requested retraction.

76. Prior to their published journal article and interview comments, Defendants knowingly and purposely avoided and ignored evidence establishing the falsity of the information they published and provided in the subsequent interviews when the

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overwhelming review of the scientific literature in the public domain stated Acacia rigidula and other acacia species naturally contained b-methylphenylethylamine, a phenylethylamine alkaloid, and that Plaintiff's products did not contain synthetic BMPEA.

77. Evidencing a reckless disregard for truth or falsity, Defendants published accusations against Plaintiff and other manufacturers that clearly contradict known scientific facts of the natural presence of b-methylphenylethylamine in acacia rigidula and other acacia species and stated that BMPEA was a synthetic additive ingredient.

78. Prior to the publication of the false and defamatory statements, Defendants knew or should have known of the natural presence of b-methylphenylethylamine, a phenylethylamine alkaloid, in acacia rigidula and other acacia species.

79. Evidencing a reckless disregard for truth or falsity, Defendants published accusations against Plaintiff without conducting even a cursory investigation to discover whether Plaintiff's products had been tested for safety (historically or clinically), which failure constitutes gross negligence.

80. Defendants had actual knowledge that the accusations against Plaintiff were false prior to publication.

81. Defendants' journal article, interviews and online comments with the media are accessible to Georgia residents, consumers, and third parties who do business

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with Plaintiff. Defendants' allegations have been published and read by third parties all across Georgia, the United States and the world.

82. Plaintiff is therefore entitled to recover its aforementioned damages as well as punitive damages from Defendants.

### **COUNT III: SLANDER**

83. Plaintiff Hi-Tech re-alleges and incorporates by reference herein Paragraphs1 through 82 above.

84. Defendants verbally communicated the false and defamatory accusations against Plaintiff as set forth above.

85. Defendants verbally communicated the false and defamatory accusations against Plaintiff as set forth above without any statutory, common law, or constitutional privilege.

86. The false and defamatory accusations against Plaintiff verbally disseminated by Defendant were subsequently republished worldwide and on numerous Internet websites.

87. Defendants' interviews and verbal communications contain the following false or misleading statements regarding the Acacia rigidula products containing b-methylphenylethylamine:

(a) That the amphetamine isomer b-methylphenylethylamine (BMPEA) was first synthesized in the early 1930's, but its efficacy and safety in humans has not been studied;

- (b) That Acacia rigidula is "a new replacement for ephedra . . .but in fact, it does not have that plant in it at all. It has new, designer stimulant called BMPEA";
- (c) That supplement products containing Acacia rigidula are potentially deadly. "Let's not wait until we have a body count," he said. "Just get the job done";
- (d) That BMPEA remained known only as a research chemical until early 2013;
- (e) That BMPEA has never been identified or extracted from Acacia rigidula, a shrub native to Southwestern United States and Mexico;
- (f) That FDA should immediately warn consumers about BMPEA and take aggressive enforcement action to eliminate BMPEA in dietary supplements;
- (g) That the efficacy and safety of BMPEA has never been studied in humans; therefore, BMPEA's effect on human health is entirely unknown;
- (h) That BMPEA has not been sold as a food or supplement and, therefore, is not a legitimate supplement ingredient;
- (i) That consumers should be advised to avoid all supplements labeled as containing Acacia rigidula;
- (j) That "Acacia rigidula is code in the industry for a potent synthetic stimulant,..." "They are using the name as a cover ";
- (k) That "BMPEA has never been found in Acacia rigidula or any other plant";
- That "[t]his is a brand new drug being placed into a number of supplements under the guise of a natural ingredient";
- (m) That "BMPEA is in a sense, being tested on buyers,..." "The consumer becomes the guinea pig"; and
- (n) That "we should [not] be sitting around waiting for someone to die before we take something off of the market that shouldn't have been there in the first place."

88. The verbal communications of Defendants as set forth above constitute slander in violation of O.C.G.A. § 51-5-4.

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89. The verbal communications of Defendants as set forth above constitute slander per se in that they impute criminal activity to Plaintiff.

90. The verbal communications of Defendants as set forth above constitute slander per se in that they impute actions to Plaintiff that injure its business reputation.

91. The verbal communications of Defendants as set forth above constitute slander per se in that they impute actions to Plaintiff that are defamatory and injurious to its reputation on their face and can be so understood without reference to any additional or extrinsic facts.

92. Defendants' false and defamatory verbal statements set forth above have caused and will continue to result in damage to Hi-Tech's consumer sales, brands, sales in the raw material and contract manufacturing divisions, reputation and goodwill with regulatory authorities, vendors, business partners and customers.

93. Defendants' false and defamatory verbal statements set forth above are the direct and proximate cause of the damages alleged above.

94. At least ten (10) days prior to the filing of this action, Defendants were informed that their communications regarding the subject matter herein were false and defamatory and were requested to retract their statements. Evidencing a reckless disregard for truth or falsity, Defendants intentionally disregarded and ignored the requested retraction.

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95. Prior to their published journal article and interview comments, Defendants knowingly and purposely avoided and ignored evidence establishing the falsity of the information they published and provided in the subsequent interviews when the overwhelming review of the scientific literature in the public domain stated Acacia rigidula and other acacia species naturally contained b-methylphenylethylamine and that Plaintiff's products did not contain synthetic BMPEA, a phenylethylamine alkaloid.

96. Evidencing a reckless disregard for truth or falsity, Defendants made verbal accusations against Plaintiff and other manufacturers that clearly contradicted known scientific facts of the natural presence of b-methylphenylethylamine in acacia rigidula and other acacia species and stated that BMPEA was a synthetic additive ingredient.

97. Prior to the publication of the false and defamatory statements, Defendants knew or should have known of the natural presence of b-methylphenylethylamine, a phenylethylamine alkaloid, in Acacia rigidula and other Acacia species.

98. Evidencing a reckless disregard for truth or falsity, Defendants made verbal accusations against Plaintiff without conducting even a cursory investigation to discover whether Plaintiff's products had been tested for safety (historically or clinically), which failure constitutes gross negligence.

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99. Defendant had actual knowledge that their verbal accusations against Plaintiff were false prior to publication.

100. Defendants' journal article, interviews and other verbal comments were and are accessible to Georgia residents, consumers, and third parties who do business with Plaintiff. Defendants' allegations have been published and read by third parties all across Georgia, the United States and the world.

101. Plaintiff is therefore entitled to recover for the aforementioned damages, as well as punitive damages from Defendants.

# COUNT IV PERMANENT INJUNCTIVE RELIEF

102. Hi-Tech re-alleges and incorporates by reference herein Paragraphs 1 through101 above.

103. For the reasons stated above, Hi-Tech asserts a claim for permanent injunctive relief to prevent the ongoing harm to Hi-Tech's brands, business reputation, and goodwill.

104. As shown from the facts above, unless Defendants are permanently restrained from further dissemination of defamatory, false and misleading information, Hi-Tech will continue to suffer reputational injury and lost income.

105. Plaintiff Hi-Tech does not have an adequate remedy at law for all of damages caused by Defendants. Unless the injunctive relief requested herein is granted, it

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will suffer continue to suffer irreparable harm by the Defendants' false and defamatory communications about its products.

### **PRAYER FOR RELIEF**

106. Hi-Tech therefore requests the Court to enter judgment in its favor and grant the following relief:

(a) Trial by jury;

(b) An award of special and compensatory damages in an amount to be determined at trial, against Defendants and in favor of Hi-Tech for the injury to its commercial reputation and business as a result of the disparaging and defamatory statements made by Defendants Cohen, Bloszies, Yee, and Gerona; and that judgment be entered against Defendant for compensatory damages in an amount of at least Fifty Million Dollars (\$50,000,000.00);

(c) That judgment be entered against Defendants for punitive damages in an amount not less than One Hundred and Fifty Million Dollars (\$150,000,000.00) to punish and penalize Defendants and deter Defendants from repeating this unlawful conduct;

(d) That Defendants be ordered to publish a retraction of the articles and interviews and any other written or oral communication made by Defendants about Plaintiff's products;

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(e) That all costs of this action be assessed against Defendant including attorneys' fees;

(f) That Plaintiff be granted an assessment of pre-judgment and postjudgment interest on the recovered damages;

(g) That permanent injunctive relief be granted ordering Defendants Cohen, Bloszies, Yee, and Gerona, their agents, attorneys, servants, employees, and other persons in active concert or participation with them, including the officers, directors, and employees of *Drug Testing and Analysis*, to:

(1) Cease directly or indirectly publishing the defamatory statements contained on the *Drug Testing and Analysis* journal, and/or inviting or inciting others to republish the defamatory statements;

(2) Remove all content from the *Drug Testing and Analysis* scientific journal that is published by John Wiley & Sons and any abstracted and/or indexed references in Chemical Abstract Services, EMBASE, MEDLINE/PUBMED, Science Citation Index Expanded, and Scopus; and cease publishing same, while strictly preserving such electronic evidence for consideration and use in further Court proceedings; and,

(h) Judgment in Hi-Tech's favor on all counts of the Complaint; and that this Court award such other relief as it deems equitable, just, and proper.

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# JURY TRIAL DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure and all applicable

law, Plaintiff requests a trial by jury on all issues so triable.

Dated: April 28th, 2015

Respectfully submitted,

<u>S/ Edmund J. Novotny</u> Edmund J. Novotny, Jr. Georgia Bar No. 547338 Charles R. Bridgers Georgia Bar No. 080791 *Counsel for Plaintiff Hi-Tech Pharmaceuticals, Inc* 

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