IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BEFORE Brands, Inc. d/b/a SpoonfulONE,	)	
Plaintiff,	)	
v.	)	C.A. No. 21-1706-CFC
Prollergy Corporation d/b/a Ready, Set, Food!,	)	
Defendant.	)	

SECOND AMENDED COMPLAINT

Plaintiffs, BEFORE Brands, Inc. d/b/a SpoonfulONE ("SpoonfulONE"), and the Board of Trustees of the Leland Stanford University ("Stanford") (collectively, "Plaintiffs"), by and through its attorneys, for its complaint against Defendant Prollergy Corporation d/b/a Ready, Set, Food! ("RSF" or "Defendant"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 271, *et seq.*, to enjoin infringement and obtain damages resulting from Defendant's unauthorized manufacture, use, sale, offer to sell and/or importation into the United States for subsequent use or sale of products that infringe one or more claims of U.S. Patent Nos. 9,731,003 ("the '003 Patent")

and 11,278,615 ("the '615 Patent") (collectively, "the patents-in-suit," and attached as Exhibits A and B, respectively) both entitled "Mixed Allergen Compositions And Methods For Using The Same." Plaintiffs seek injunctive relief to prevent Defendant from continuing to infringe the patents-in-suit. In addition, Plaintiffs seek a recovery of monetary damages resulting from Defendant's past and continued infringement of these patents.

2. This action for patent infringement involves Defendant's manufacture, use, sale, offer for sale, and/or importation into the United States of infringing mixed allergen composition products including, but not limited to, RSF's "Stage 3" food mix-in product, comprising nine allergen flours and powders including walnut, peanut, cashew, almond, milk, wheat and sesame, and the "Organic Baby Oatmeal" product comprising the same nine allergens flours or powders (collectively, the "Accused Products").

3. Additionally, this is an action for false advertising arising under Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), to enjoin false advertising and to obtain damages resulting from Defendant's false claims in its online advertisements, packaging, and other marketing materials that have misled consumers into choosing Defendant's products over SpoonfulONE's. SpoonfulONE seeks injunctive relief to prevent Defendant from falsely advertising regarding the Stage 3 Product. In addition, SpoonfulONE seeks a recovery of

monetary damages resulting from Defendant's false advertising of the Stage 3 Product.

4. Finally, this is an action for deceptive trade practices arising under 6 Del. C. § 2532 to enjoin deceptive trade practices and to obtain damages resulting from Defendant's deceptive marketing tactics including, but not limited to, false representations regarding the characteristics and ingredients of the Stage 3 Product. Plaintiffs seek injunctive relief to prevent Defendant from continuing to deceive consumers and harm SpoonfulONE's business. In addition, SpoonfulONE seeks a recovery of monetary damages resulting from Defendant's pattern of deceptive trade practices.

5. The actions for false advertising and deceptive trade practices involve Defendant's online advertising including, but not limited to, on its website (https://readysetfood.com/), its official Instagram account (@readysetfood), in SMS text messages, and on product listing pages on Amazon.com, which claim and/or claimed that the Stage 3 Product "contain[s] a total of 2 g of protein per week for each allergen with the exception of egg whites," which Defendant has admitted to be literally false.

THE PARTIES

6. Plaintiff SpoonfulONE is a corporation organized and existing under the laws of the State of Delaware. Its principal place of business is located at 125 Willow Road, Suite 200, Menlo Park, CA 94025.

7. Plaintiff Stanford is a trust possessing corporate power organized under the laws of California, including, but not limited to, Education Code Section 94000 et seq, with a principal place of business at 450 Jane Stanford Way, Building 10, Stanford, CA 94305.

8. Defendant RSF is a corporation organized and existing under the laws of the State of Delaware. Its principal place of business at 15821 Ventura Boulevard, Suite 450, Encino, Los Angeles, CA 91436.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this patent infringement and false advertising action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. Defendant is subject to personal jurisdiction in this judicial district because it is incorporated in Delaware and because it regularly transacts business in this judicial district by, among other things, selling and offering for sale its mix-in products, including the Accused Products, to customers located in this judicial district. Defendant has also committed acts of infringement of one or more claims of the patent-in-suit in this judicial district.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b) because Defendant is incorporated in this district.

FACTUAL BACKGROUND

SpoonfulONE and Its Inventive Mixed Allergen Compositions, as Claimed in the Patents-in-Suit

12. Since 2015, SpoonfulONE has been a leading provider of nutritional products intended to protect babies from developing a food allergy. The company's products are incorporated into the diet of infants around four months of age as part of solid food introduction, enabling families to provide balanced, gentle, and consistent immune system training to their infants.

13. SpoonfulONE owns or has rights to multiple patents and pending patent applications directed to mixed allergen compositions. SpoonfulONE is diligent in protecting and enforcing its intellectual property.

14. Plaintiff SpoonfulONE sells its products under the brand name SpoonfulONE.

15. SpoonfulONE products have been on the market since 2017.

16. On August 15, 2017, the '003 Patent was duly and legally issued for an invention entitled "Mixed Allergen Compositions And Methods For Using The Same."

17. On March 22, 2022, the '615 Patent was duly and legally issued for an invention entitled "Mixed Allergen Compositions And Methods For Using The Same."

18. Dr. Kari Nadeau is one of the world's leading pediatric allergists and immunologists and the Director of the Sean N. Parker Center for Allergy and Asthma Research at Stanford University. She is the inventor of the patents-in-suit.

19. Dr. Nadeau co-founded SpoonfulONE in 2015. As the inventor and co-founder of SpoonfulONE, Dr. Nadeau had the vision to make multi-allergen introduction easy and safe for parents.

20. The patents-in-suit are directed to mixed allergen compositions comprising multiple different allergens.

21. The invention of the patents-in-suit is advantageous because it is directed to combining multiple flours and powders, including nut allergens, animal allergens, and non-nut allergens, for use in a variety of applications, including combatting food allergies. By combining multiple different allergens, the invention helps combat multiple food allergies in the same composition. Food allergies are an epidemic—to this day, hundreds of people die annually in the United States due to fatal food allergies and billions of dollars are spent per year on healthcare for food allergic reactions. As explained in the patents-in-suit, "1 out of 12 children under the age of 21 years of age have a doctor's diagnosis of food allergies. . . . Moreover,

there are still deaths that occur every year due [to] fatal food allergies. Importantly, over $24 billion is spent per year on healthcare/care costs for food allergic reactions. . . . This cost is largely due to about 90,000 visits to the ER per year in the U.S. due to food induced anaphylactic symptoms." The invention of the patents-in-suit helps fight this epidemic.

22. Stanford owns all rights, title, and interest in and to the patents-in-suit among other patents and patent applications.

23. SpoonfulONE has a license to the patents-in-suit and intellectual property pursuant to the Second Amended and Restated Exclusive (Equity) Agreement it executed with Stanford effective as of September 24, 2019. SpoonfulONE has an exclusive license in the field of foods and dietary substances, including but not limited to all rights to make, use, and sell the technology claimed in the patents-in-suit, to sublicense the patents-in-suit, and to institute suit against third parties for infringement of the patents-in-suit.

24. SpoonfulONE's allergen mix-in products practice one or more claims of the patents-in-suit.

25. Pursuant to the license, SpoonfulONE pays Stanford royalties on Net Sales of its products that practice one or more claims of the patents-in-suit.

RSF's Infringing Products and Harm to SpoonfulONE

26. On information and belief, Defendant RSF began operations on or about 2018, and launched its Stage 3 mix-in product in March 2021.

27. Defendant promotes, offers for sale, and sells its allergen mix-in products online through an Internet website accessible at https://readysetfood.com/.

28. Defendant also promotes, offers for sale, and sells its allergen mix-in products online via Amazon and online and in stores via the retailer Buy Buy Baby.

29. Defendant's advertisements for the Stage 3 Product state that the Stage 3 Product will "[i]ntroduce the top 9 allergens to your baby mixed into any food they eat" comprising peanut, milk, cashew, almond, walnut, sesame, soy, and wheat.

30. Defendant's advertisements for the Organic Baby Oatmeal product state that customers can substitute the Stage 3 product for the Organic Baby Oatmeal product and that it "has the same allergens" as the Stage 3 product, namely "peanut, egg, milk, cashew, almond, walnut, sesame, soy, wheat."

31. On April 21, 2021, SpoonfulONE sent a letter to Defendant to notify Defendant of SpoonfulONE's intellectual property portfolio and to inform Defendant of its infringement of the '003 Patent.

32. Defendant did not respond to SpoonfulONE's April 21, 2021 letter.

33. SpoonfulONE sent a follow-up letter on September 14, 2021 to reiterate the information contained in its previous letter and to provide an update on the

prosecution of other patents within SpoonfulONE's portfolio, specifically the application that subsequently issued as the '615 Patent.

34. Defendant's counsel responded to SpoonfulONE's September 14, 2021 letter by stating only that "we do not believe that the Stage 3 formulation infringes," without providing any explanation or support for that position.

35. Defendant has made, used, sold and/or offered for sale within the United States, and/or imported into the United States, allergen mix-in products, including but not limited to the Stage 3 product, that infringe at least claim 9 of the '003 Patent.

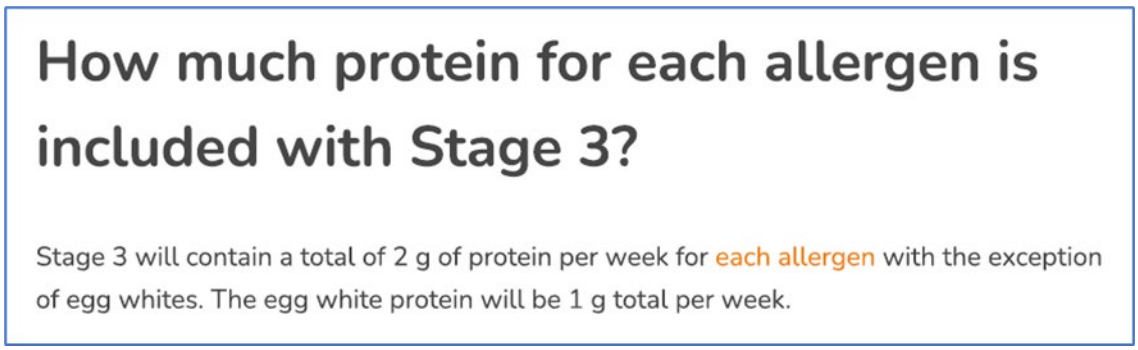
36. Defendant has made, used, sold and/or offered for sale within the United States, and/or imported into the United States, allergen mix-in products, including but not limited to the Accused Products, that infringe at least claim 2 of the '615 Patent.

37. SpoonfulONE is being irreparably harmed by Defendant's infringement of its valuable patent rights. Moreover, Defendant's unauthorized infringement of SpoonfulONE's patent rights is threatening the value of this intellectual property because Defendant's conduct results in SpoonfulONE's loss of its lawful patent rights to exclude others from making, using, selling, offering to sell, and/or importing the patented inventions.

RSF's False and Misleading Advertising

38. Defendant advertises and offers for sale the Accused Products on its website.

39. At least until December 13, 2021, RSF's advertisement and/or offer for sale of the Stage 3 Product in its "FAQ" page stated as follows: "Stage 3 will contain a total of 2 g of protein per week for each allergen with the exception of egg whites." A true and correct copy of the this advertisement and/or offer for sale is copied here:



40. On December 16, 2021, counsel for SpoonfulONE brought the above-referenced FAQ to counsel for RSF's attention. Counsel for RSF responded: "I have discussed the FAQ that you sent below with my client. ***They said that the information was incorrect*** and took it down." (emphasis added).

41. Defendant also operates product listing pages on Amazon.com. Defendant continues to advertise and/or offer for sale on Amazon.com that the Stage 3 comprises equal parts of protein by weight, despite Counsel's representation that the false or "incorrect" FAQ had been taken down. A true and correct copy of the Amazon advertisement and/or offer for sale for the Stage 3 Product is as follows:

0 votes

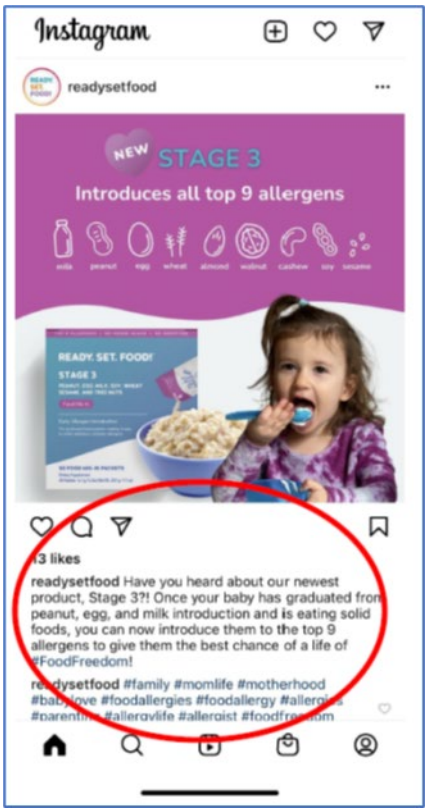
Question: The infographic shows the doses of milk, egg increasing over several days - where can I find this info (doses/# of days) for the 9 stage 3 allergens?

Answer: Stage 3 will not have an individual introduction to all 9 allergens. It will be a combined mixture of all allergens starting with the first packet. Stage 3 will contain a total of 2 g of protein per week for each allergen with the exception of egg whites. The egg white protein will be 1 g total per week.

By Ready, Set, Food! SELLER on November 2, 2021

42. In correspondence dated February 11, 2022, counsel for RSF wrote, "To be clear, at no time did RSF use equal parts by protein weight," again admitting that RSF's advertisement and/or offer for sale regarding the protein weight of the Stage 3 Product was knowingly false.

43. Defendant advertises on the Stage 3 Product's packaging that it contains the "[t]op 9 allergens." Defendant also makes the same claim on its website, Amazon.com product page, and official Instagram account. The following are examples:



1 vote

Question: This is advertised as including the top 9 allergens which are peanut, egg, milk, soy, wheat, sesame, tree nuts, fish and shellfish. Where is the fish?

Answer: We included the top 9 childhood food allergens with Stage 3 which does not include fish and shrimp. Shrimp and fish food allergies are commonly developed as an adult.
By Ready, Set, Food! SELLER on April 28, 2021

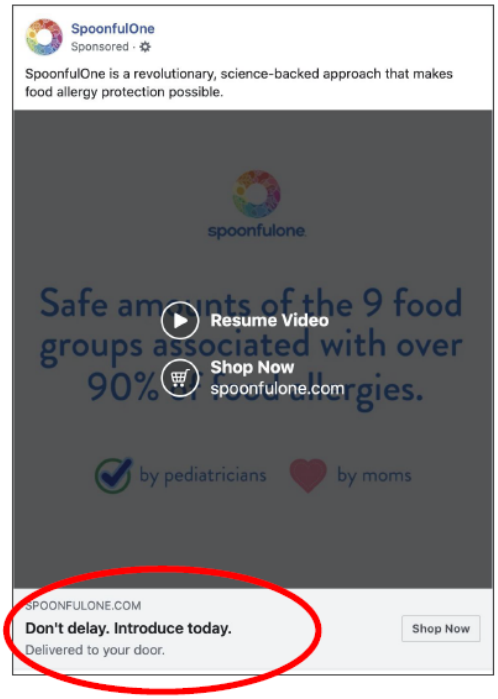
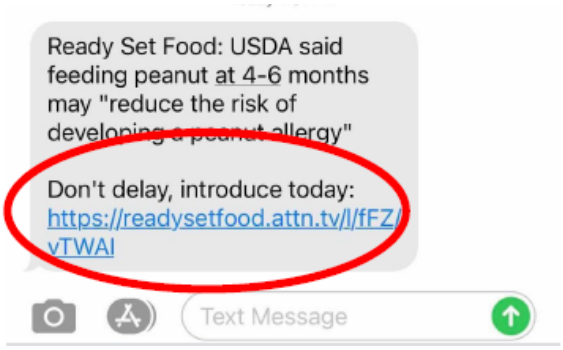
44. The claim that the Stage 3 Product contains the top 9 allergens is false or at least misleading because the Stage 3 Product does not contain fish and shellfish. The "top 9 allergens" as defined by the Food Allergen Labeling and Consumer Protection Act of 2004 includes fish and shellfish.

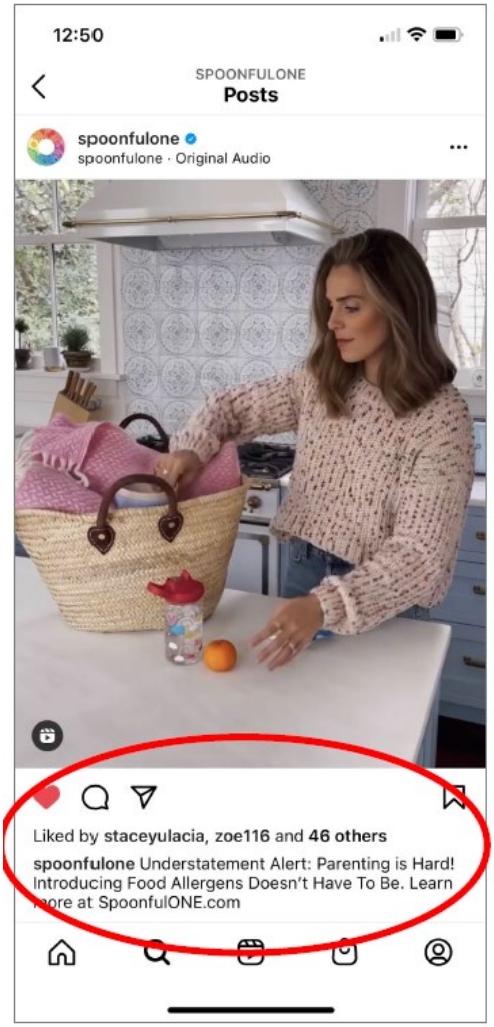
45. Defendant knowingly falsely or misleadingly advertises that the Stage 3 Product contains the top 9 allergens. This is at least because, in an FAQ on the

Amazon.com Stage 3 product listing, Defendant acknowledges that the top 9 allergens include fish and shellfish, which the Stage 3 Product does not have.

46. Defendant, throughout its advertisements, has used themes, colors, slogans, and motifs that closely resemble SpoonfulONE's advertisements. On information and belief, consumers are confused by Defendant's similar branding and conflate the products from the two brands. The following are visual examples of RSF's deliberate mimicking of SpoonfulONE's branding and advertisements in a way that misleads consumers:

SpoonfulONE	**RSF**
	

SpoonfulONE	**RSF**
	

SpoonfulONE	**RSF**
	

47. Defendant, through its affiliate Prevent Food Allergies (at preventallergies.org), has made false and disparaging statements regarding SpoonfulONE's products. For example, in a chart comparing the Stage 3 Product with SpoonfulONE's product, it lists SpoonfulONE's product as containing only nine allergens when in fact it contains 16 allergens.

48. On information and belief, Defendant's false and misleading advertising and marketing statements have caused actual deception or at least a tendency to deceive a substantial portion of consumers who buy such products. Defendant's deception is material in that it is likely to influence consumers' purchasing decisions. By falsely advertising that RSF's product is of similar quality

to SpoonfulONE's patented technology, RSF has deceived consumers into believing the company's products to be of comparable quality.

49. SpoonfulONE has been injured by Defendant's false advertising, including loss of sales and goodwill. SpoonfulONE and RSF are the only two companies in the market offering multi-allergen compositions in a multi-staged and portion-controlled format. As such, SpoonfulONE is in direct competition with RSF for these products. On information and belief, SpoonfulONE has lost sales to RSF because of its false advertisements.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 9,731,003

50. Paragraphs 1-49 are incorporated by reference as if fully restated herein.

51. Defendant's Stage 3 Product infringes at least claim 9 of the '003 Patent.

52. The Stage 3 Product is a mixed allergen composition comprising at least six different flours or powders.

53. The Stage 3 Product contains at least one flour selected from the group consisting of walnut, hazelnut, peanut, cashew, almond, pistachio, and pecan; specifically, the Stage 3 Product contains walnut, peanut, cashew, and almond flours.

54. The Stage 3 Product contains at least one animal powder selected from the group consisting of shrimp, salmon, egg, and milk; specifically, the Accused Product contains milk powder.

55. The Stage 3 Product contains at least one non-nut plant flour selected from the group consisting of wheat, sesame, and oat; specifically, the Stage 3 Product contains wheat and sesame flours.

56. On information and belief, the unit composition of the Stage 3 Product comprises equal parts by protein weight of the following eight flours or powders: walnut, peanut, cashew, almond, milk, wheat, soy, and sesame. At a minimum, Defendant offered for sale the Stage 3 Product as comprising equal parts by protein weight of the following eight flours or powders: walnut, peanut, cashew, almond, milk, wheat, soy, and sesame.

57. Defendant's acts of direct infringement has caused damage to Plaintiffs, and Plaintiffs are entitled to recover from Defendant the damages sustained by Plaintiffs as a result of Defendant's wrongful acts in the amount subject to proof at trial. Defendant's infringement of SpoonfulONE's exclusive rights under the '003 Patent will continue to damage SpoonfulONE's business, causing irreparable harm for which there is no adequate remedy at law, unless Defendant is enjoined by this Court.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 11,278,615

58. Paragraphs 1-57 are incorporated by reference as if fully restated herein.

59. Defendant's Accused Products infringe at least claim 2 of the '615 Patent.

60. The Accused Products are both mixed allergen compositions of 9 allergen flours or powders.

61. The Accused Products contain walnut flour, cashew flour, almond flour, peanut flour, sesame flour, soy flour, wheat flour, and milk powder.

62. On information and belief, the Accused Products contain 0.1% and 15% by protein weight of each of the allergen flours and powders described in ¶ 61 above, or an equivalent thereof.

63. The Accused Products contain a vertebrate animal powder selected from the group consisting of salmon powder, egg powder, or cod powder; specifically, the Accused Products contain egg powder.

64. Defendant's acts of direct infringement have caused damage to Plaintiffs, and Plaintiffs are entitled to recover from Defendant the damages sustained by Plaintiffs as a result of Defendant's wrongful acts in the amount subject to proof at trial. Defendant's infringement of SpoonfulONE's exclusive rights under

the ’615 Patent will continue to damage SpoonfulONE’s business, causing irreparable harm for which there is no adequate remedy at law, unless Defendant is enjoined by this Court.

COUNT III

FALSE ADVERTISING UNDER 15 U.S.C. § 1125

65. Paragraphs 1-64 are incorporated by reference as if fully restated herein.

66. Defendant has made false or misleading statements regarding the Stage 3 Product, advertising it as comprising equal parts by protein weight of walnut, peanut, cashew, almond, milk, wheat, soy, and sesame flours, which Defendant has admitted was false.

67. Defendant has knowingly made and continues to make false or misleading statements regarding the Stage 3 Product, advertising it as containing the “[t]op 9 allergens,” which Defendant knows it does not have.

68. Defendant, through an affiliate, has made false and disparaging statements regarding SpoonfulONE’s product as only containing 9 allergens when it in fact contains 16.

69. Defendant, throughout its advertisements, has used themes, colors, slogans, and motifs that closely resemble SpoonfulONE’s advertisements, which confuse consumers.

70. On information and belief, Defendant's conduct has caused actual deception or at least a tendency to deceive a substantial portion of consumers who buy such products.

71. On information and belief, Defendant's deception is material in that it is likely to influence consumers' purchasing decisions.

72. Defendant sells the Stage 3 Product on its website, Amazon.com, and through other national retailers that offer delivery in all 50 states. At least for that reason, the Stage 3 Product is sold in interstate commerce.

73. Defendant's acts of false advertising have caused damage to SpoonfulONE and SpoonfulONE is entitled to recover from Defendant the damages sustained by SpoonfulONE as a result of Defendant's wrongful acts in the amount subject to proof at trial. Defendant's false and misleading advertisements will continue to lead consumers astray and damage SpoonfulONE's business, causing irreparable harm for which there is no adequate remedy at law, unless Defendant is enjoined by this Court.

COUNT IV

DECEPTIVE TRADE PRACTICES UNDER 6 DEL. C. § 2532

74. Paragraphs 1-73 are incorporated by reference as if fully restated herein.

75. Defendant, in its course of business, has falsely advertised and/or continues to falsely advertise that the ingredients of the Stage 3 Product comprise equal parts by protein weight of walnut, peanut, cashew, almond, milk, wheat, soy, and sesame flours. Defendant has admitted through counsel that the advertised composition of the Stage 3 Product ingredients is false.

76. Defendant, in its course of business, has also falsely or misleadingly advertised the Stage 3 Product as containing the "top 9 allergens," and continues to do so. Defendant has admitted through advertising that this statement is at least misleading.

77. Accordingly, Defendant has made representations about the characteristics and ingredients of its goods that the goods do not have in violation of at least 6 Del. C. § 2532(a)(5).

78. Defendant, throughout its advertisements, has used themes, colors, slogans, and motifs that closely resemble SpoonfulONE's advertisements, which causes a likelihood of confusion in violation of at least 6 Del. C. § 2532(a)(2)-(3).

79. Defendant, through its affiliate, has made false and disparaging statements regarding SpoonfulONE's products in violation of at least 6 Del. C. § 2532(a)(8).

80. Defendant knew or should have known that its conduct described above constituted unfair and deceptive trade practices that are prohibited by 6 Del. C. § 2532.

81. SpoonfulONE is entitled to damages for Defendant's unfair and deceptive trade practices described above.

82. Defendant's conduct has damaged SpoonfulONE, and caused and continues to cause it irreparable harm. SpoonfulONE is likely to be injured by Defendant's conduct in the form of declining sales and/or lost goodwill. SpoonfulONE has no adequate remedy at law.

83. SpoonfulONE is entitled to an injunction pursuant to 6 Del. C. § 2533(a) prohibiting further acts of unfair competition, since it will continue to suffer immediate and irreparable harm if Defendant's conduct is not enjoined.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That this Court adjudge and decree that the Defendant has directly infringed the '003 Patent by selling or offering to sell the Stage 3 Product;

B. That this Court adjudge and decree that the Defendant has directly infringed the '615 Patent by selling or offering to sell the Accused Products;

C. That this Court permanently enjoin Defendant and its subsidiaries, affiliates, successors and assigns and each of their officers, directors, agents,

servants, employees, licensees, and all persons acting in concert or active participation with them, or on their behalf, or within their control, from engaging in any acts that constitute infringement of the ’003 Patent or the ’615 Patent;

D. That this Court adjudge and decree that the Defendant has falsely advertised their products to the detriment of SpoonfulONE;

E. That this Court permanently enjoin Defendant and its subsidiaries, affiliates, successors, and assigns and each of their officers, directors, agents, servants, employees, licensees, and all persons acting in concert or active participation with them, or on their behalf, or within their control, from engaging in any acts that constitute false advertising;

F. That this Court adjudge and decree that the Defendant has committed deceptive trade practices by making false claims regarding its products to the detriment of SpoonfulONE;

G. That this Court permanently enjoin Defendant and its subsidiaries, affiliates, successors, and assigns and each of their officers, directors, agents, servants, employees, licensees, and all persons acting in concert or active participation with them, or on their behalf, or within their control, from engaging in any acts that constitute deceptive trade practices;

H. That this Court order an accounting, including a post-verdict accounting, to determine the damages to be awarded to Plaintiffs as a result of Defendant's infringement;

I. That this Court, pursuant to 35 U.S.C. § 284, enter an award to Plaintiffs of such damages as it shall prove at trial against Plaintiffs that are adequate to compensate SpoonfulONE for said infringement, false advertising, and deceptive trade practices, such damages to be no less than a reasonable royalty for said infringement, and no less than lost profits for its false advertising and deceptive trade practices, all together with interest and costs;

J. That this Court assess pre-judgment and post-judgment interest and costs, together with an award of such interest and costs;

K. That this Court award Plaintiffs their costs and attorneys' fees in this action pursuant to 15 U.S.C. § 1117(a) and/or 35 U.S.C. § 285, or as otherwise provided by law; and

L. That Plaintiffs be awarded such further relief as this Court may deem just and appropriate.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury of all matters to which it is entitled to a trial by jury pursuant to Federal Rule of Civil Procedure 38.

/s/ Karen E. Keller
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