IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

RIVER'S EDGE PHARMACEUTICALS, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CIVIL ACTION**
	)	**FILE NO._____**
BROOKSTONE PHARMACEUTICALS, LLC, a Delaware Corporation, and JR NUTRACEUTICALS, INC.	)	
	)	
Defendants.	)	
_____	)	

COMPLAINT

DEMAND FOR JURY TRIAL

COMES NOW Plaintiff River's Edge Pharmaceuticals, LLC, a Georgia limited liability company ("River's Edge") and files this Complaint, showing as follows:

PARTIES AND JURISDICTION

1. Plaintiff is engaged in the marketing and sale of prescription pharmaceuticals.

2. Defendant Brookstone Pharmaceuticals, LLC ("Brookstone") is a Delaware Limited Liability Company with its principal place of business at 9005 Westside Parkway, Alpharetta, Fulton County, Georgia 30009. Brookstone may be served with Summons and Complaint through its registered agent, Kevin J. Loechl at 1150 Monarch Plaza, 3414 Peachtree Road, NE, Atlanta, Fulton County, Georgia 30326.

3. Defendant JR Nutraceuticals Inc. ("JR") is a New York corporation with its principal place of business at 1885 New Highway Suite 1, Farmingdale, New York

11735-1518. JR may be served with process through its registered agent, Spiegel & Utrera, P.A., P.C., 1 Maiden Lane, 5th Floor, New York, New York, 10038.

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 1338, in that claims asserted in this Complaint arise under the laws of the United States relating to patents and trademarks. This Court has supplemental jurisdiction over the state law claims asserted in this action pursuant to 28 U.S.C. §§ 1338(b) and 1367, in that the state law claims asserted in this Complaint are so related to the claims asserted under federal law as to form part of the same case or controversy under Article III of the United States Constitution.

5. This Court has personal jurisdiction over Brookstone in that it has continuously and systematically offered to sell, offers to sell, has sold and/or sells products to wholesalers, distributors and retailers in this judicial district, has engaged and continues to engage in acts of false advertising, unfair competition and intentional interference in this judicial district, and this controversy is related to and arises out of Brookstone's advertising and sale of products within the forum state.

6. Plaintiff is informed and believes, and on that basis avers, that this Court has personal jurisdiction over JR because it manufactured and sold infringing products to Brookstone with the specific knowledge, intent and expectation that those products would be sold through to wholesalers, distributors and retailers in this judicial district.

7. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), in that (1) both defendants are deemed to reside in this jurisdiction pursuant to 28 U.S.C. § 1391(c)

because they are subject to personal jurisdiction in this judicial district; and (2) a substantial part of the events and omissions that give rise to this action occurred in this judicial district.

U.S. PATENT NO. 6,979,468

8. On December 27, 2005, U.S. Patent 6,979,468 ("the '468 Patent"), titled "Oral Composition and Method for the Treatment of Inflammatory Cutaneous Disorders" was duly and validly issued to the inventor Frank Pollard. A copy of the '468 Patent is attached as **Exhibit A**.

9. The '468 Patent covers pharmaceutical preparations for the treatment of inflammatory skin conditions such as acne rosacea and acne vulgaris including an immediate release form of nicotinamide in combination with a sustained release form of zinc.

10. River's Edge is the exclusive licensee of the '468 Patent, and has the right and standing to pursue claims for infringement. River's Edge manufactures and sells covered products called Nicomide and Nicotinamide ZCF.

11. Neither Brookstone nor JR holds any license under the '468 Patent and neither has the right to manufacture or sell a product that infringes the '468 Patent.

12. Plaintiff is informed and believes, and on that basis avers, that JR, at the direction of Brookstone, has manufactured, sold and offered for sale, and continues to manufacture, sell and offer for sale a product called Nicotinamide Zinc Oxide, Cupric Oxide, Folic Acid Tablets ("Defendants' Product").

13. According to the information insert included with each package of Defendants' Product, Defendants' Product includes cupric oxide in an immediate release form and zinc oxide in a "delayed action" form, "indicated for non-pregnant patients with acne vulgaris, acne rosacea or other inflammatory skin disorders."

14. Plaintiff is informed and believes, and on that basis avers, that the "delayed action" form of zinc in Defendants' Product is in a sustained release form and therefore infringes the '468.

15. Plaintiff is informed and believes, and on that basis avers, that Brookstone has directed JR to manufacture Defendants' Product, has placed orders for the Defendants' Product, and has sold, or offered to sell, Defendants' Product to wholesalers, distributors, drug store chains, and pharmacies in this judicial district and throughout the country, including at least CVS, Walgreens, Kroger, and Publix, all of which infringe in Plaintiff's rights. Plaintiff is further informed and believes, and on that basis avers, that Defendants intend to continue theses infringing actions and will do so unless and until enjoined by this Court.

16. Plaintiff is informed and believes, and on that basis avers, that to induce wholesalers and national accounts to purchase Defendants' Product, Brookstone has contacted national pharmaceutical databases and supplied those databases with information inaccurately detailing and describing the Defendants' Product as possessing the attributes of, and to be lawfully substitutable for, Nicotinamide ZCF.

17. Plaintiff is informed and believes, and on that basis avers, that national

pharmaceutical databases such as Medi-Span/Wolters Kluwer and First DataBank have, in reliance on the false information submitted to them by Defendants, placed the Subject Product in the same product category as Nicotinamide ZCF, causing dispensing pharmacists to substitute Defendants' Product for Nicotinamide ZCF.

18. Plaintiff is informed and believes, and on that basis avers, that Defendants' representations to the database companies to the effect that Defendants' Product has the same attributes as Nicotinamide ZCF constitute false advertising and false or misleading descriptions of fact that are likely to cause confusion and mistake, in violation of 15 U.S.C. § 1125(a)(1)(A) and (B), because the quantities of the active ingredients in Defendant's Product are substantially higher than the quantities of the same ingredients in Nicotinamide ZCF.

DEFENDANTS' SCHEME TO EVADE REGULATION

19. The federal Food and Drug Administration ("FDA") has the authority to promulgate rules and regulations governing the manufacturing and sale of prescription medications.

20. At all relevant times, FDA Rules and Regulations have required manufacturers of prescription products to manufacture their products pursuant to Current Good Manufacturing Processes ("CGMP"). 21 CFR § 211.

21. At all relevant times, CGMP for prescription products have required that all prescription products be subjected to rigorous testing protocols, including testing for appropriate methods, packaging, process, and stability. In addition, CGMP require that

manufacturers perform validation to ensure that the testing that they perform is valid.

22. By manufacturing, marketing or selling medications as prescription medications, a party explicitly and implicitly represents that the product has been subjected to the minimum CGMP for the products as set forth in 21 CFR § 211 *et seq*.

23. Plaintiff is informed and believes, and on that basis avers, that prior to entering into its current arrangement with Brookstone as manufacturer of Defendants' Product, JR was engaged exclusively in the business of manufacturing nutritional supplements, products that are not subject to the CGMP established by FDA regulations for prescription products.

24. Plaintiff is informed and believes, and on that basis avers, that Defendants have created a scheme by which they have sought to avoid the requirements of 21 CFR § 211 *et seq.*, but to create the false impression that they have complied with the FDA's rules and regulations for manufacturing and distributing prescription products.

25. Specifically, Plaintiff is informed and believes, and on that basis avers, that JR manufactures Defendants' Product as if it were a nutritional supplement, Defendants deliver Defendants' Product to an independent packaging company that packages and labels Defendants' Product for sale as if it were a prescription product, and then Brookstone sells Defendants' Product as a prescription pharmaceutical to wholesalers, distributors, drug store chains, and pharmacies who are misled into believing that Defendants' Product had been manufactured and distributed pursuant to the FDA Rules and Regulations applicable to prescription products.

26. As a result, wholesalers, distributors, drug store chains, pharmacies and the customers to whom Brookstone sells Defendants' Product are led to believe that Defendants' Product has, among other things, been subjected to stability testing, packaging validation, process validation and that the testing that has been done to reach these conclusions has itself been scientifically validated, when it has not.

CLAIM I: INFRINGEMENT OF THE '468 PATENT

27. Plaintiff incorporates and repeats the averments of ¶¶ 1-26 as if set forth here in full.

28. Defendants' Product is labeled as containing the following active ingredients in the stated amounts:

Each oral tablet provides:
Nicotinamide, USP……..……750 mg
Zinc oxide, USP…….25 mg
Cupric Acid……...……1.5 mg
Folic Acid, USP……...……..500 mcg

29. The '468 Patent includes the following claims:

1. An oral pharmaceutical preparation in dosage unit form adapted for administration for the treatment of inflammatory skin disorders, comprising, per dosage unit, at least 250 mg of nicotinamide in an immediate release form, and an amount of zinc in a sustained release form, said amount of zinc being sufficient to provide an enhanced anti-inflammatory effect, in a vehicle pharmaceutically acceptable for oral administration.

2. The oral pharmaceutical preparation of claim 1 wherein said zinc is present as zinc oxide, zinc sulfate, zinc gluconate, zinc complexes or zinc chelates.

3. The oral pharmaceutical preparation of claim 2 wherein said zinc is present as zinc oxide in the amount of about at least 15 mg per dosage unit.

4. The oral pharmaceutical preparation of claim 3 wherein said zinc oxide is present in the amount of about at least 20 mg per dosage unit.

5. The oral pharmaceutical preparation of claim 4 wherein said zinc oxide is present in the amount of about at least 25 mg per dosage unit.

6. The oral pharmaceutical preparation of claim 1 further comprising an amount of folic acid.

7. The oral pharmaceutical preparation of claim 6 wherein said folic acid is present in the amount of at least about 500 micrograms per dosage unit.

8. The oral pharmaceutical preparation of claim 1 wherein said nicotinamide is present in the amount of about at least 500 mg per dosage unit.

9. The oral pharmaceutical preparation of claim 1 wherein said nicotinamide is present in the amount of about at least 750 mg per dosage unit.

10. The oral pharmaceutical preparation of claim 1 further comprising an amount of a copper-containing compound.

11. The oral pharmaceutical preparation of claim 10 wherein said copper-containing compound is in an immediate release form.

12. The oral pharmaceutical preparation of claim 10 wherein said copper-containing compound is selected from the group consisting of cupric oxide, cupric sulfate, copper complexes and copper chelates.

13. The oral pharmaceutical preparation of claim 10 wherein said copper-containing compound is present in an amount of about at least 1.0 milligrams per dosage unit.

14. The oral pharmaceutical preparation of claim 13 wherein said copper-containing compound is present in an amount of about at least 1.5 milligrams per dosage unit.

15. The oral pharmaceutical preparation of claim 1 wherein each dosage unit is in the form of a tablet, capsule or softgel.

30. Defendants' Product infringes claims 1 through 15 of the '468 Patent.

31. Defendants' infringement has deprived Plaintiff of the benefits of its patent rights, and has caused damages in an amount that is not yet known, but is believed to exceed $250,000 per month that Defendants' Product has been and remains on the market in unlawful competition with Plaintiff's products.

32. Unless enjoined by this Court, Defendants' acts will continue to irreparably injure Plaintiffs' goodwill and erode its market share. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing acts.

CLAIM II: VIOLATION OF 15 U.S.C. § 1125(a)

33. Plaintiff incorporates and repeats the averments of ¶¶ 1-32 as if set forth here in full.

34. Defendants' explicit and implicit promotional claims about Defendants' Product are literally and impliedly false and misleading.

35. JR has aided and abetted Brookstone's deceitful actions with full knowledge, or in reckless disregard, of Brookstone's intent to promote and market Defendants' Product as if it were a prescription pharmaceutical.

36. Defendants' implicit and explicit claims violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), subsection (1) of which provides:

> Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false

> or misleading description of fact, or false or misleading representation of fact, which (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

37. Buyers of Defendants' Product have no choice in many circumstances but to trust that Defendants' Product does possess the attributes claimed for it by Defendants.

38. Plaintiff has been injured by Defendants' actions and representations because customers who would otherwise have purchased from Plaintiffs have made, or will make, purchasing decisions based upon Defendants' false and misleading representations concerning the attributes of Defendants' Product.

39. Based on their false assertions, Defendants have caused drug wholesalers, distributors, drug store chains, pharmacies, and others to stock and sell Defendants' Product and to demand that Plaintiff reduce the price of Plaintiff's own product to meet Defendants' price.

40. Brookstone is using in commerce, with the knowledge and consent of JR, false or misleading descriptions of fact or misleading representations of fact concerning the nature, characteristics, and qualities of Defendants' Product.

41. Brookstone's false, deceptive, and misleading advertising has the capacity to deceive customers and is likely to influence customers' purchasing decisions, thereby harming Plaintiffs.

42. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendants' Lanham Act violations, an accounting of profits made by Defendants on Defendants' Product, as well as recovery of costs of this action.

43. Each Defendant is contributorily and vicariously liable for the Lanham Act violations of the other because each knew of, or had reason to know of, the false and misleading advertising, marketing, and promotion of Defendants' Product, yet aided and abetted those violations.

44. Defendants' acts are willful, wanton, and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Plaintiffs to recover additional damages and reasonable attorney fees pursuant to 15 U.S.C. § 1117.

45. Unless enjoined by this Court, Defendants' acts will irreparably injure Plaintiffs' goodwill and erode its market share. Pursuant to 15 U.S.C. § 1116, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing acts.

CLAIM III: TORTIOUS INTERFERENCE WITH CONTRACTUAL RELATIONS AND BUSINESS RELATIONS

46. Plaintiff incorporates and restates the allegations of paragraphs 1- 45 of this Complaint as if fully set forth here.

47. Brookstone has contacted River's Edge's customers and potential customers, falsely claiming that Defendants' Product is a prescription medication, expressly or impliedly stating that it is manufactured in accordance with federal regulations governing the manufacturing of prescription medications.

48. In conjunction with those false statements, Brookstone negotiated pricing with CVS, Walgreens, Kroger, and Publix (and others) that was substantially less than the pricing contractually agreed between River's Edge and its customers.

49. River's Edge's customers indicated that they would terminate their contracts with River's Edge unless River's Edge beat or met the pricing offered by Brookstone.

50. Plaintiff is informed and believes, and on that basis avers, that JR has aided and abetted Brookstone's actions by manufacturing Defendants' Product with, at most, only the lower quality controls appropriate to nutritional supplements, and has benefited thereby.

51. Plaintiff is informed and believes, and on that basis avers, that Brookstone has recently sent letters to River's Edge's customers stating:

> Brookstone is using a fully approved manufacturer for our alternative to the brand **Nicomide**. You will interested to know that River's Edge lists NeilGen as the manufacturer of their Nicotinamide ZCF on the MSDS sheet and the pills are imprinted with "NL" to signify the source. According to April 10th FDA notice:
>
> > "The U.S. Food and Drug Administration today announced that it had obtained a permanent injunction barring Neilgen Pharmaceuticals Inc. of Westminster, Md., its parent company, Advent Pharmaceuticals, Inc. (Advent), of East Windsor, N.J., and two of their officers, Bharat Patel and Pragna Patel, from manufacturing and distributing any unapproved, adulterated or misbranded drugs."

52. The accusations contained within Defendants' letters are false.

53. The text of the letters contains false and defamatory allegations and

innuendo concerning River's Edge.

54. The letters are intended to damage and defame River's Edge's professional character, trade, office, and profession and subjecting it to contempt and ridicule.

55. The letters were intended to induce River's Edge's customers to cease doing business with River's Edge and instead do business with Defendants.

56. Plaintiff is informed and believes, and on that basis avers, that the letters were understood by its recipients.

57. Plaintiff is informed and believes, and on that basis avers, that the letters were written and published without any good faith basis or privilege upon which to make the false statements set forth in them.

58. Plaintiff is informed and believes, and on that basis avers, that Brookstone wrote and published the letters out of malice, with knowledge of the falsity of the statements, and/or a reckless disregard or serious doubt as to whether they were true or false, with the intent to injure River's Edge and its business reputation, and further to interfere with any contractual or other potential business relationship that River's Edge may have had with each intended recipient of the letters.

59. Defendants acted purposely, with malice, and with the intent to injure River's Edge.

60. Defendants' actions induced a substantial modification of the contractual obligations and business relations between River's Edge and its customers, causing River's Edge substantial damages in an amount not yet known as the damages continue to

increase, but to be proved at trial.

CLAIM IV: DEFAMATION BY BROOKSTONE

61. Plaintiff incorporates and restates the allegations of paragraphs 1- 60 of this Complaint as if fully set forth here.

62. As a result of the Brookstone's letters to River's Edge's customers and potential customers, River's Edge has sustained damages including, but not limited to, injury to business reputation, arising from and proximately caused by the publication of the defamatory letters.

63. Brookstone is liable to River's Edge for damages and injuries, including injury to River's Edge's good name, reputation, and standing arising from the libelous and defamatory publications described above.

64. Brookstone is liable to River's Edge for general and special damages proximately caused by the defamation in an amount to be determined at trial.

CLAIM V: VIOLATION OF MINN. STAT. § 325D.43 *et seq.* (UNIFORM DECEPTIVE TRADE PRACTICES ACT)

65. Plaintiffs incorporate and restate the allegations of paragraphs 1-64 as if fully set forth here.

66. A person engages in deceptive trade practices in violation of the Minnesota U.D.T.P. (Minn. Stat. § 325D.44) when the person:

> (2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
> . . . .
> (5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not

> have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;
> . . . .
> (7) represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
>
> (8) disparages the goods, services, or business of another by false or misleading representation of fact; [or]
>
> (9) advertises goods or services with intent not to sell them as advertised.

67. Brookstone, aided and abetted by JR, has engaged in deceptive trade practices with respect to explicit and implicit representations to drug wholesalers, distributors, drug store chains, pharmacies, consumers and others regarding Defendants' Product.

68. Defendants' false representations are likely to cause confusion, mistake, or deception about the characteristics, quality, grade and certification of the Defendants' Product.

69. Defendants know, or in the exercise of reasonable discretion should know, that the inaccurate implicit and explicit representations in their marketing has resulted, and will continue to result, in purchasing decisions in their favor that would otherwise favor Plaintiff.

70. Defendants' actions are willful and have been undertaken for the purpose of deceiving customers, and Plaintiff has been damaged thereby.

71. As a result of such conduct, Defendants have caused and unless enjoined by this Court will continue to cause, consumer confusion as to the quality of Defendants'

Product.

72. Pursuant to Minn. Stat. § 325D.45, Plaintiff is entitled to an injunction enjoining Defendants from unfair competition and an award of its attorneys' fees.

WHEREFORE, Plaintiff prays for judgment:

(a) For an accounting of profits made by Defendants;

(b) For damages in the amount proved at trial;

(c) For a preliminary and permanent injunction enjoining Defendants from further infringement, unfair competition and unfair and deceptive conduct;

(d) For costs;

(e) For attorneys' fees to the extent permitted by applicable law;

(f) For pre-judgment and post-judgment interest to the extent permitted by applicable law;

(g) For enhanced or punitive damages to the extent permitted by applicable law; and

(h) For such further relief as this Court deems just.

DEMAND FOR JURY TRIAL

Plaintiff River's Edge Pharmaceuticals, LLC, hereby demands trial by jury of all counts triable to a jury.

This 10th day of July, 2009.

Respectfully submitted,

/s/ Sara Bottleson Turner
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