UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

PAMLAB, L.L.C. and MERCK & CIE	)	CASE NO. ___
	)	
Plaintiffs,	)	SECTION __
	)	
v.	)	MAGISTRATE DIV. ___
	)	
TRIGEN LABORATORIES, INC.,	)	**JURY DEMANDED**
	)	
Defendant.	)	

ORIGINAL COMPLAINT

Plaintiffs Pamlab, LLC ("Pamlab") and Merck & Cie ("Merck") file this Complaint against Defendant TriGen Laboratories, Inc. ("TriGen") and allege as follows:

1. This is an action for a permanent injunction and for further relief based on patent infringement under 35 U.S.C. § 271, false advertising and unfair competition under Section 43(a) of the Lanham Act, and/or common law unfair competition.

PARTIES

2. Plaintiff Merck is a Swiss corporation with a principal place of business at Im Laternenacker 5, CH-8200 Schaffhausen, Switzerland. Merck exclusively licenses United States Patent Nos. 6,254,904; 6,451,360; 6,673,381; 6,808,725; 7,172,778; and 7,674,490 ("patents in suit") from South Alabama Medical Science Foundation ("SAMSF"), the patent owner. SAMSF has granted Merck and Merck's sublicensees the right to commence a patent infringement action involving the patents-in-suit.

3. Plaintiff Pamlab is a limited liability company organized under the laws of Louisiana, having its principal place of business in Covington, St. Tammany Parish, Louisiana. Pamlab is a fully integrated pharmaceutical company that specializes in the development of prescription medical foods that are marketed and sold nationally. Among its products Pamlab

markets are: CEREFOLIN®, CEREFOLIN NAC®, NEEVO®, NEEVO DHA®, (the "Pamlab Products") which address the distinct nutritional requirements of patients with problem pregnancies and with early memory loss. Pamlab holds a sublicense for an exclusive field of use from Merck under Patent Nos. 6,254,904; 6,451,360; 6,673,381; 6,808,725; 7,172,778; and 7,674,490 to use Merck's patented Metfolin®.

4. Defendant TriGen is a corporation organized under the laws of New Jersey and having its principal place of business at 2400 Main Street Extension, Suite 6, Sayreville, New Jersey 08872. Defendant TriGen markets, promotes, advertises, offers for sale, sells and/or distributes products including: Rovin-NV; Rovin-NvDHA; Rovin-CF OF; and Triveen-CF NAC (the "TriGen Products") to customers including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations and/or others throughout the United States, including in Louisiana. Defendant TriGen may be served with process through its Registered Agent, Mike Hudy, at 104 Union Avenue (Rt 71), Manasquan, New Jersey 08736.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, 35 U.S.C. § 271 et seq. Accordingly, the Court has jurisdiction over this matter under 28 U.S.C. §§ 1331 and 1338(a). In addition, this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1332, 1338, and 1367, and 15 U.S.C. §§ 1116 and 1121 under the Lanham Act. Additionally, the amount in controversy exceeds $75,000 and involves citizens of different states.

6. The exercise of personal jurisdiction in Louisiana is proper because acts giving rise to Plaintiffs' causes of action have occurred in the State of Louisiana and, more particularly, within the Eastern District of Louisiana. More specifically, TriGen markets, promotes, advertises, offers for sale, sells and/or distributes the TriGen Products to customers including

wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations, and/or others throughout the United States, including in Louisiana. Defendant has purposefully and voluntarily placed the TriGen Products into the stream of commerce with the expectation that they will be purchased by consumers in Louisiana. Consumers have purchased and continue to purchase the TriGen Products in Louisiana. Furthermore, TriGen falsely promotes the TriGen Products as a generic equivalent to and substitute for NEEVO®, NEEVO DHA®, CEREFOLIN® and/or CEREFOLIN NAC® to customers including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations, and/or others throughout the United States, including in Louisiana.

7. Venue is proper in Louisiana under 28 U.S.C. § 1391.

BACKGROUND

Merck Successfully Synthesized Folic Acid into Metafolin®

8. Merck is the Swiss affiliate of Merck KGaA and provides active pharmaceutical and dietary ingredients to the pharmaceutical and nutritional industry for use in clinical trials and commercial product applications. Merck is acclaimed worldwide for its novel drugs and therapeutic products. Merck's products are some of the most well-known and well-respected medical and dietetic products worldwide.

9. Among its many inventions, Merck successfully synthesized folic acid into a stable and substantially pure form of L-methylfolate – the body's preferred form of folate – which is able to cross the blood-brain barrier without further bioconversion by the body.[1] Merck

[1] Methylfolate can occur in two forms – L and D. The L form is the naturally occurring predominant form of folate that is found in food and in the human body.

markets this unique form of L-methylfolate under the trade name Metafolin®. Metafolin® is not folic acid, but rather it is a distinct dietary ingredient achieved through a unique and innovative method that yields L-methylfolate in a stable and substantially pure form.

10. Specifically, Metafolin® is the dietary ingredient (6S)-N-[4-[[(2-aminio-1,4,5,6,7,8-hexahydro-5- methyl-4-oxo -6-pteridinyl) methyl] amino]benzoyl]-L-glutamic acid, calcium salt. It is also known as L-5-methyltetrahdrofolic acid, calcium salt; L-methylfolate; (6S)-5-MTHF; or L-5-MTHF (hereinafter, "L-methylfolate"). Merck filed a New Dietary Ingredient Notification with the United States Food and Drug Administration ("FDA") in 2001 for its dietary ingredient L-methylfolate.

11. L-methylfolate is particularly useful because some people carry a genetic alteration (termed a "polymorphism") in one or both genes of an enzyme involved in folic acid metabolism that affects their ability to metabolize folic acid. Approximately 9 to 22% of patients carry the double alteration, while 44% have a single alteration. These patients get lower folate levels from folic acid and are at increased risk for neural tube defects and other folate related conditions. L-methylfolate avoids the problem of folic acid metabolism deficiencies.

12. Merck supplies L-methylfolate as a bulk substance. Merck's licensees and customers then use Metafolin® brand L-methylfolate in various dietary supplements, medical foods, nutritional supplements, prenatal vitamins, and food for special dietary use. Merck's L-methylfolate complies with all applicable requirements for dietary ingredients established by the FDA and its product adheres to industry specifications for L-methylfolate.

13. Over the years, Merck has spent many millions of dollars researching and developing its L-methylfolate, and devotes significant financial resources each year to marketing

its product. Merck has conducted extensive clinical and laboratory trials and testing on its L-methylfolate. Merck receives substantial revenue from its L-methylfolate dietary ingredient.

Pamlab Developed CEREFOLIN®, CEREFOLIN NAC®, NEEVO®, NEEVO DHA®, to Help Millions of Americans Who May Be Subject to Problem Pregnancies or Suffering from Early Memory Loss

14. Pamlab is an integrated specialty pharmaceutical company with development and commercial capabilities focused primarily on prescription medical foods. Among its specific focus areas are the development of therapies for patients who may be subject to problem pregnancies and/or suffering from early memory loss.

15. Since 2002, Pamlab has licensed one or more of the patents-in suit from Merck, which has an exclusive license to the patents-in-suit. Pamlab currently exclusively licenses the patents-in-suit in a specific Field of Use that generally includes Medical Foods, Foods for Special Dietary Use, Prenatal and/or Postnatal Prescription Vitamins. Products made, used or sold by Pamlab in the United States under this license are subject to payment of a royalty on net sales to Merck.

16. Each of the Pamlab Products use Merck's L-methylfolate product as an active ingredient. Unlike medical foods containing folic acid that must undergo several metabolic steps before it can be used in the body, the Pamlab Products provide the active form of folate, L-methylfolate, to patients. The Pamlab Products' use of L-methylfolate is a unique selling point Pamlab uses to market the products.

17. Pamlab began marketing CEREFOLIN® in March of 2004. CEREFOLIN®'s formulation provides L-methylfolate, along with vitamin B_2 (riboflavin), vitamin B_6 (pyridoxine), and vitamin B_{12} (cyanocobalamin). CEREFOLIN® is used to manage the distinct nutritional requirements of individuals under treatment for early memory loss with particular emphasis for

those individuals diagnosed with or at risk for neurovascular oxidative stress and/or hyperhomocysteinemia, mild to moderate cognitive impairment with or without vitamin B_{12} deficiency, vascular dementia or Alzheimer's disease. CEREFOLIN® combats progressive memory loss by supporting the synthesis of acetylcholine, an important neurotransmitter associated with memory. CEREFOLIN® has been shown to be effective for reducing the effects of oxidative stress in the brain, and improving cognitive behavior and mental reaction time.

18. Pamlab began marketing an enhanced formula of CEREFOLIN® called CEREFOLIN NAC® in March of 2006. CEREFOLIN NAC® is an orally administered prescription medical food for the dietary management of certain metabolic processes identified with early memory loss. CEREFOLIN NAC®'s manages the distinct nutritional requirements of people suffering from early memory loss, particularly in those diagnosed with or at risk for neurovascular oxidative stress and/or hyperhomocysteinemia, mild to moderate cognitive impairment, vascular dementia or Alzheimer's disease. Oxidative stress leads to memory loss. The theory behind CEREFOLIN NAC®'s effectiveness may be related to its ability to reduce the effects of oxidative stress that result from reduced antioxidant levels that occur with age.

19. Pamlab began marketing NEEVO® in January of 2007. NEEVO® is a medical food for use only under medical supervision for the dietary management of impaired metabolic processes in women who face high to intermediate risk pregnancies and are unable to fully metabolize or absorb folic acid. NEEVO® helps mothers-to-be in the formation of new DNA. It is also used to reduce the risk of having a baby with a serious birth defect of the brain and spinal cord called a "neural tube defect." NEEVO® has been shown to be an effective supplement for pregnant women wishing to lower the risk that their babies will have these neural tube defects.

20. Pamlab began marketing NEEVO DHA® in March of 2009. NEEVO DHA® is a multivitamin/multi-mineral nutritional supplement for women who require increased vitamin, mineral and essential fatty acid concentrations throughout pregnancy and the post natal period for both lactating and non-lactating mothers. It can be used prior to conception to improve nutrition. It has become one of the nation's fastest growing and largest prescription prenatal vitamins.

21. Pamlab has expended substantial resources developing the Pamlab Products. In addition, Pamlab's representatives have met with doctors and other prescribers not only to provide information on the use and benefits of the Pamlab Products, but also to provide doctors with samples of the Pamlab Products. Pamlab's efforts have succeeded to the extent that its sales of the Pamlab Products are expected to be almost $35,000,000 in 2010.

22. Each of the Pamlab Products practices, and is marked with, at least one of the patents-in-suit.

Defendant Develops and Markets Their Knock-Off Product to Exploit Pamlab's Success

23. TriGen is a New Jersey-based "specialty niche pharmaceutical company" that markets and sells what it describes as generic pharmaceuticals. TriGen does not market its alleged generic equivalent drug products to physicians. Rather, it convinces drug wholesalers, distributors, pharmacies, pharmacists and national drug databases that its products are generic substitutes for brand-name drugs. Its sales result from "generic" substitution of its products for brand-name drugs.

24. TriGen advertises, promotes, markets, sells and distributes its products nationwide, including in Louisiana and this judicial district.

25. Sometime in 2010, TriGen saw an opportunity to exploit the reputation and success of the Pamlab Products by creating the TriGen Products, knock-offs of the Pamlab Products. Specifically, TriGen began distributing, marketing, selling and/or offering for sale Rovin-Nv, Rovin-Nv DHA, Rovin-Cf OF, and Triveen-CF NAC as alleged generic equivalent substitutes for NEEVO®, NEEVO® DHA, CEREFOLIN® and CEREFOLIN NAC®, respectively.

Defendant Markets The TriGen Products as Generic Substitutes for NEEVO®, NEEVO DHA®, CEREFOLIN® AND CEREFOLIN NAC®

26. TriGen seeks to capture market share from Pamlab by encouraging generic substitution of the TriGen Products for the respective Pamlab Products. In its commercial advertising and promotion to drug databases, wholesalers, pharmacies, pharmacists and others in the pharmaceutical distribution chain, TriGen has made no effort to differentiate the TriGen Products from the Pamlab Products other than on the basis of price.

27. Defendant advertises and promotes the TriGen Products in labeling and elsewhere as having the same active ingredients in the same amounts as the respective Pamlab Products. Specifically, Defendant advertises and promotes the TriGen Products as containing L-methylfolate, in the exact same amounts contained in the Pamlab Products. Defendant advertises and promotes the TriGen Products to drug wholesalers, distributors, pharmacies, pharmacists and others as a generic equivalent to and substitute for the respective Pamlab Products.

28. Defendant has caused their knock-off products to be linked to respective Pamlab Products in drug databases. The drug databases are a major marketing communications channel to drug wholesalers, pharmacies and others, and are used by pharmacists to decide which drug product to dispense when filling a prescription.

29. Defendant's efforts have had their intended effect; based upon Defendant's commercial advertising and promotion, drug databases as well as wholesalers, pharmacies and others "linked" the TriGen Products as a generic equivalent to the respective Pamlab Products. As a result of Defendant's commercial advertising and promotion, some wholesalers and pharmacies in the Eastern District of Louisiana and across the country have ceased to purchase the Pamlab Products, purchasing the TriGen Products instead, believing they are a generic substitute. Moreover, pharmacists in the Eastern District of Louisiana and across the country dispense the TriGen products as generic substitutes for the Pamlab Products. This could not occur unless Defendant had successfully created the false impression among drug databases, wholesalers, pharmacies, pharmacists and others in the pharmaceutical distribution chain that the TriGen Products contain L-methylfolate in the same amounts as the Pamlab Products and are genuinely generic to, and substitutable for, the Pamlab Products.

The TriGen Products do not contain the claimed strength of L-methylfolate and are not Generic Equivalents to, nor a Substitute for the Pamlab Products

30. A pharmacist presented with a doctor's prescription for a brand-name product may fill that prescription by dispensing the product prescribed or an identical, "generic" version of the product. This process is known as generic substitution.

31. A generic product is identical – or therapeutically equivalent – to a brand name product in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Therapeutically equivalent products are both pharmaceutical equivalents and bioequivalents.

32. Products are considered to be pharmaceutical equivalents if they: (1) contain the same active ingredient(s); (2) are of the same dosage form and route of administration; and (3)

are identical in strength or concentration. They must also meet identical standards of quality, purity and potency.

33. Products are considered bioequivalent products if they deliver the active ingredients to the bloodstream at the same rate and with the same level of absorption. Bioequivalence ensures that a generic product substituted for the prescribed brand-name product is truly interchangeable and will provide the patient with the treatment the doctor ordered.

34. Thus, pharmacists and other medical professionals expect that a product advertised, promoted and sold as a generic will be pharmaceutically equivalent, bioequivalent and therapeutically equivalent to the brand.

35. Notwithstanding Defendant's advertising and promotion, the TriGen Products do not contain the same active ingredients in the same strengths as the Pamlab Products and are not generic equivalents to, or substitutes for, the Pamlab Products. Defendant does not license or use a stable, crystalline L-methylfolate, as Pamlab does, but instead uses a cheaper, unstable, form of this ingredient that degrades more rapidly. Because of this, the TriGen Products in the market contain less than the advertised amount of L-methylfolate. Additionally, because the TriGen Products do not actually contain the identical active ingredients in the same amounts as the Pamlab Products they are not pharmaceutically equivalent to or generic substitutes for the Pamlab Products.

36. Defendant has not published or, upon information and belief, performed or commissioned any studies demonstrating that the TriGen Products deliver their active ingredients to patients at the same rate and in the same amount as the Pamlab Products. In the absence of testing, the TriGen Products cannot be presumed to be bioequivalent and therapeutically

equivalent to the Pamlab Products. Indeed, the TriGen Products are not therapeutically equivalent to the Pamlab Products.

TriGen's Claimed Expiration Date is False

37. Defendant has further promoted the TriGen Products to drug wholesalers, retailers, pharmacists and others as stable products having an established expiration date two years after the date of manufacture. The expiration date on pharmaceutical products indicates how long those products can be expected to retain their potency. Promoting a product with an expiration date constitutes a representation that appropriate testing has been performed to support the conclusion that the product will continue to meet its label claims for that period of time. This information is a critical selling point for pharmaceutical products.

38. Drug wholesalers, retailers, pharmacists and others have relied on defendant's advertised expiration date in deciding to buy, stock and dispense the TriGen Products.

39. However, based on testing, the TriGen Products shelf life is significantly shorter than the advertised two (2) years. Indeed, the TriGen Products were out of specification within two (2) to three (3) months of being placed into the stream of commerce. Because of this, patients are not receiving the level of folate that has been prescribed by their health care provider.

40. Plaintiffs have been and will continue to be harmed by Defendant's literally and impliedly false and misleading advertising and unfair competition. Defendant's marketing efforts have misled consumers into believing that the TriGen Products are a generic equivalent to and substitute for the respective Pamlab Products. As a result, substitutions of the TriGen Products for the respective Pamlab Products have eroded and will continue to erode Pamlab's sales and goodwill as well as Pamlab's and Merck's revenues.

41. Plaintiffs do not and cannot control the safety, effectiveness, or quality of Defendant's product. Thus, doctors and patients who suffer bad experiences with the TriGen Products that are substituted for prescriptions of the Pamlab Products are likely to think less of both Plaintiffs and the Pamlab Products.

COUNT ONE

Literal Infringement, or under the Doctrine of Equivalence, of United States Patent Nos. 6,254,904; 6,451,360; 6,673,381; 6,808,725; 7,172,778; and 7,674,490

42. Plaintiffs refer to and incorporate herein the allegations of Paragraphs 1-42.

43. The United States Patent and Trademark Office duly and legally issued the following patents: U.S. Patent 6,254,904 on July 3, 2001 (Exhibit 1); U.S. Patent 6,451,360 on September 17, 2002 (Exhibit 2); U.S. Patent 6,673,381 on January 6, 2004 (Exhibit 3); U.S. Patent 6,808,725 on October 26, 2004 (Exhibit 4); U.S. Patent 7,172,778 on February 6, 2007 (Exhibit 5); and, U.S. Patent 7,674,490 on March 9, 2010 (Exhibit 6) (collectively "patents-in-suit"). Merck is the exclusive licensee of the patents-in-suit, and Pamlab exclusively sublicenses them for a particular field of use from Merck.

44. The patents-in-suit are valid and enforceable.

45. Upon information and belief, Defendant has been and is now directly infringing, and/or actively inducing infringement by others, and/or contributing to the infringement by others of U.S. Patent Nos. 6,254,904; 6,451,360; 6,673,381; 6,808,725; 7,172,778; and 7,674,490 in this District, and elsewhere in the United States. The patents have been infringed literally and/or under the doctrine of equivalents.

46. Upon information and belief, Defendant has been (a) making, using, selling, offering to sell, importing and/or having had made or used a product that is the subject of the

patents-in-suit and/or (b) making, using, offering for sale, selling and/or having had made or used methods claimed in the patents-in-suit. The products constitute or are contained in at least one of the Trigen Products, and the methods involve the Trigen Products.

47. Upon information and belief, by making, using, selling, offering to sell, and/or importing in or into the United States, without authority, products that fall within the scope of at least one of the patents-in-suit, Defendant has also induced infringement of at least one of the patents-in-suit under 35 U.S.C. § 271(b), and have contributed to the infringement of at least one of the patents-in-suit under 35 U.S.C. § 271(c). The infringing products have no substantial non-infringing uses.

48. Defendant has actively infringed, induced infringement and/or contributed to the infringement and is still actively infringing, inducing, and/or contributing to the infringement of the patents-in-suit, and will continue to do so unless enjoined by the Court.

49. Pamlab's Products are marked with U.S. Patent 6,254,904, in compliance with 35 U.S.C. Section 287.

50. Plaintiffs have suffered and are suffering monetary damages from Defendant’s unauthorized infringement that are compensable under 35 U.S.C. § 284 in an amount to be determined at trial or hearing.

51. Plaintiffs have been irreparably harmed by Defendant’s acts of infringement of the patents-in-suit and will continue to be harmed unless and until Defendant’s acts of infringement are permanently enjoined and restrained by order of this Court.

52. Upon information and belief, Defendant’s infringement of the patents-in-suit has been and continues to be willful and deliberate, making this an exceptional case entitling

Plaintiffs to recover additional damages and reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT TWO

False Advertising – Lanham Act § 43(a), 15 U.S.C. § 1125(a)

53. To the extent not inconsistent with, or in the alternative, Plaintiffs refer to and incorporate herein the allegations of Paragraphs 1-52, the same as if set forth at length.

54. Defendant markets the TriGen Products to drug information databases and consequently to drug wholesalers, distributors, pharmacies and pharmacists, and others in interstate commerce as containing L-methylfolate in the same amounts as the Pamlab Products. Defendant intends for drug information databases and pricing systems to link the TriGen Products as a pharmaceutically equivalent and substitute product for the Pamlab Products. Defendant intends for drug wholesalers, distributors, pharmacies and pharmacists to rely on this information and to form the belief that the TriGen Products are generically equivalent to and substitutable for the respective Pamlab Products, and on that basis to provide patients whose doctors have prescribed the Pamlab Products the TriGen Products instead. Defendant also advertises and promotes the TriGen Products as a stable product with a twenty-four month shelf life.

55. Defendant's advertisements and promotional claims about the TriGen Products are literally and/or impliedly false and misleading. The TriGen Products do not contain L-methylfolate in the amounts claimed on the labels. The TriGen Products are not pharmaceutically equivalent, bioequivalent, generic to or substitutable for the respective Pamlab Products. The TriGen Products are not stable and do not have a twenty-four month shelf life. Defendant's promotional claims violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), which

provides in relevant part that "any person who, on or in connection with any goods or services, . . . uses in commerce any . . . false or misleading description of fact or misleading representation of fact, which . . . 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 to a civil action by any person who believes that he or she is likely to be damaged by such act."

56. Additionally, Defendant is liable for false advertising under the Lanham Act because it intentionally induced and/or knew or had reason to know that drug databases, wholesalers, pharmacies, pharmacists and others in the pharmaceutical distribution chain would falsely describe the TriGen Products as generics to and a substitutes for the respective Pamlab Products to pharmacists, but continued to sell the products to those entities.

57. By reason of Defendant's conduct, Plaintiffs have suffered and will continue to suffer, damage to their businesses, reputations and goodwill. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendant's Lanham Act violations, an accounting of profits made by Defendant on sales of the TriGen Products and recovery of Plaintiffs' costs and reasonable attorneys' fees incurred in this action.

58. Defendant's 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 attorneys' fees pursuant to 15 U.S.C. § 1117.

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

COUNT THREE

Unfair Competition – Lanham Act § 43(a), 15 U.S.C. § 1125(a)

60. To the extent not inconsistent with, or in the alternative, Plaintiffs refer to and incorporate herein the allegations of Paragraphs 1-60, the same as if set forth at length.

61. Pamlab has become uniquely associated with NEEVO®, NEEVO DHA®, CEREFOLIN®, AND CEREFOLIN NAC® and the public identifies Pamlab as the source for NEEVO®, NEEVO DHA®, CEREFOLIN®, AND CEREFOLIN NAC®.

62. Defendant has marketed and continue to market their knock-off products as equivalents to and substitutes for NEEVO®, NEEVO DHA®, CEREFOLIN®, AND CEREFOLIN NAC®, and in doing so, have deceived, misled and confused drug wholesalers, distributors, pharmacies and pharmacists. This has enabled Defendant to trade off of Pamlab's reputation and good will. In addition, Defendant has falsely marketed and promoted the characteristics of the TriGen Products in its efforts to capitalize on Pamlab's reputation, good will and success. The TriGen Products are not pharmaceutically equivalent, generic to or substitutable for the respective Pamlab Products. The TriGen Products do not contain L-methylfolate in the amounts claimed on the labels. TriGen falsely claims and promotes that the TriGen Products have a shelf life of twenty-four months.

63. Defendant's acts constitute unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

64. By reason of Defendant's conduct, Plaintiffs have suffered and will continue to suffer damage to their businesses, reputations and goodwill. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendant's Lanham Act violations, an accounting of

profits made by Defendant on sales of TriGen Products and recovery of Plaintiffs' costs for this action.

65. Defendant's 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 attorneys' fees pursuant to 15 U.S.C. § 1117.

66. Unless enjoined by this Court, Defendant's acts will continue to cause immediate and irreparable harm to Plaintiffs for which there is no adequate remedy at law. Pursuant to 15 U.S.C. § 1116, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendant's continuing acts.

COUNT FOUR
Common Law Unfair Competition

67. To the extent not inconsistent with, or in the alternative, Plaintiffs refer to and incorporate herein the allegations of Paragraphs 1-66, the same as if set forth at length.

68. With full knowledge of NEEVO®, NEEVO DHA®, CEREFOLIN®, AND CEREFOLIN NAC®, Defendant has made false and misleading explicit and implicit representations to drug information databases and pricing systems that their product contains the same active ingredients in the same strength as NEEVO®, NEEVO DHA®, CEREFOLIN®, AND CEREFOLIN NAC® and is equivalent to and substitutable for NEEVO®, NEEVO DHA®, CEREFOLIN®, AND CEREFOLIN NAC®. Defendant has also made false and misleading explicit and implicit representations regarding the amount of L-methylfolate in the TriGen Products and has made false and misleading explicit and implicit representations regarding the shelf life of the TriGen Products. Defendant intends that these false and misleading explicit and implicit representations will be passed to drug wholesalers, distributors, pharmacies

and pharmacists, who will form the belief that Defendant's product is generic to and can be substituted for prescriptions for the respective Pamlab Products.

69. Defendant's selective and misleading comparisons of the TriGen Products with the respective the Pamlab Products, and omission of relevant facts, are likely to cause confusion, mistake or deception about the nature, characteristics and qualities of their knock-off products in comparison, connection or association with the Pamlab Products.

70. Defendant knows, or in the exercise of reasonable discretion should know, that their marketing program encourages the sale and substitution of the TriGen Products for prescriptions of the respective Pamlab Products and is likely to result in the improper substitution of the TriGen Products for the Pamlab Products, and the deception of drug wholesalers, distributors, pharmacies, pharmacists and others about the nature, characteristics and qualities of TriGen Products in comparison, connection or association with the Pamlab Products.

71. Defendant's actions are willful and have been undertaken with the purpose of deceiving consumers.

72. As a result of such conduct, Defendant has caused, and unless enjoined by this Court, will continue to cause confusion as to the equivalence and interchangeability of their knock-off product with the Pamlab Products.

73. Plaintiffs are entitled to damages for Defendant's unfair competition, an accounting of profits made on sales of the TriGen Products and recovery of Plaintiffs' costs of this action. In addition, Defendant knew or should have known that its conduct was reasonably likely to result in injury, damage or other harm, thus warranting the award of punitive damages.

74. As a result of Defendant's conduct, Plaintiffs have suffered, and unless such acts and practices are enjoined by this Court, will continue to suffer damage to their businesses, reputation and goodwill for which it is entitled to preliminary and permanent injunctive relief.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request that the Court enter judgment in their favor and against Defendant as follows:

A. A judgment that the Defendant has infringed Patent Nos. 6,254,904; 6,451,360; 6,673,381; 6,808,725; 7,172,778; and 7,674,490 as alleged herein;

B. A judgment and order that Defendant, its agents, servants, employees, representatives, successors and assigns, and those acting in privity or in concert with them, be preliminarily and permanently enjoined from further infringement of Patent Nos. 6,254,904; 6,451,360; 6,673,381; 6,808,725; 7,172,778; and 7,674,490.

C. A judgment and order requiring Defendant to pay Plaintiffs' damages in an amount to be proved at trial that will adequately compensate Plaintiffs for Defendant's infringement, but under no circumstances an amount less than a reasonable royalty, as authorized by 35 U.S.C. § 284;

D. A judgment and order increasing the damages sustained by Plaintiffs up to three times the amount of their actual damages, as authorized by 35 U.S.C. § 284;

E. A judgment and order requiring Defendant to pay Plaintiffs their attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285;

F. A judgment and order requiring Defendant to pay Plaintiffs' prejudgment interest and costs pursuant to 35 U.S.C. § 284;

G. A judgment and order that Defendant, its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, be preliminarily and permanently enjoined from placing, and are ordered to remove information linking CEREFOLIN®, CEREFOLIN NAC®, NEEVO® and/or NEEVO DHA® to the TriGen Products in any drug dispensing databases in the United States;

H. A judgment and order that Defendant include in any advertisement or promotion comparing the TriGen Products with CEREFOLIN®, CEREFOLIN NAC®, NEEVO® and/or NEEVO DHA®, whether oral or written, a notice in location and typeface as prominent as the comparison itself, that its product "is not pharmaceutically or therapeutically equivalent to CEREFOLIN®, CEREFOLIN NAC®, NEEVO® and/or NEEVO DHA®. Therefore, the substitution of this product for CEREFOLIN®, CEREFOLIN NAC®, NEEVO® and/or NEEVO DHA® may violate state law";

I. A judgment and order that Defendant takes corrective action to correct any erroneous impression persons may have derived concerning the nature, characteristics or qualities of the products or CEREFOLIN®, CEREFOLIN NAC®, NEEVO® and/or NEEVO DHA®, including without limitation the placement of corrective advertising to prevent the inducement of others from substituting the TriGen Products for prescriptions of CEREFOLIN®, CEREFOLIN NAC®, NEEVO® and/or NEEVO DHA®.

J. A judgment and order granting Plaintiffs such other relief as the Court may deem appropriate to prevent the trade and public from deriving any erroneous impression concerning the nature, characteristics, or qualities of the TriGen Products or from inducing others to substitute the TriGen Products for prescriptions of CEREFOLIN®, CEREFOLIN NAC®, NEEVO® and/or NEEVO DHA®.

K. A judgment and order requiring Defendant to pay Plaintiffs damages under 15 U.S.C. § 1117(a) in the amount of Plaintiffs' actual and consequential damages and any profits of Defendant resulting from its advertisements and marketing of its products;

L. A judgment and order requiring Defendant to pay Plaintiffs all of their reasonable attorneys' fees, costs and expenses, including those available under 15 U.S.C. §1117(a) and any other applicable law;

M. A judgment and order finding that this is an exceptional case and requiring Defendant to pay Plaintiffs additional damages equal to three times the actual damages awarded Plaintiffs pursuant to 15 U.S.C. § 1117(a), as well as all of Plaintiff's reasonable attorneys' fees under 15 U.S.C. § 1117(a) and any other applicable law;

N. A judgment and order requiring Defendant to pay Plaintiffs pre-judgment and post-judgment interest on the damages awarded; and

O. Such other and further relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand that all issues so triable be determined by jury.

Dated: November 18, 2010

Respectfully submitted,

By: *s/Corinne A. Morrison*

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