

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

PAMLAB, L.L.C.,)	
)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. _____
)	
CURA PHARMACEUTICAL COMPANY,)	
INC., BI-COASTAL PHARMACEUTICAL)	JURY TRIAL DEMANDED
CORPORATION, and ANDAPHARM, L.L.C.,)	
)	
Defendants.)	

COMPLAINT

Plaintiff PamLab, L.L.C., by and through its attorneys, states as follows for its Complaint against Defendants:

The Parties

1. Plaintiff PamLab, L.L.C. (“PamLab”) is a limited liability company existing under the laws of the State of Louisiana, with its principal place of business at 4099 Highway 190, Covington, Louisiana, 70433.

2. Defendant Cura Pharmaceutical Company, Inc. (“Cura”) is a corporation existing under the laws of the State of New Jersey, with its principal place of business at 542 Industrial Way West, Eatontown, New Jersey, 07724.

3. Defendant Bi-Coastal Pharmaceutical Corporation (“Bi-Coastal”) is a corporation existing under the laws of the State of New Jersey, with its principal place of business at 130 Maple Avenue, Red Bank, New Jersey, 07701.

4. Defendant Andapharm, L.L.C. (“Andapharm”) is a limited liability company existing under the laws of the State of Florida, with its principal place of business at 5315 NW 35th Terrace, Fort Lauderdale, Florida, 33309.

Jurisdiction And Venue

5. This Court has original jurisdiction over the subject matter of this lawsuit under 28 U.S.C. §§ 1331 and 1338(a), because it arises under the patent laws of the United States, as well as under 28 U.S.C. § 1331 and 15 U.S.C. § 1221(a), because it concerns violation of section 43 of the Lanham Act, 15 U.S.C. § 1125.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1400 and 1391 because Defendants are subject to personal jurisdiction in this district.

STATEMENT OF FACTS

The Research Leading to the Patent in Suit and the Patent License

7. Homocysteine is an amino acid and a natural byproduct of the human body’s conversion of methionine into cysteine. If a body lacks the enzyme necessary to complete that conversion, or if the body lacks vitamins such as Folic Acid, B₆ and B₁₂, the concentration of homocysteine in the blood and urine increases.

8. In recent years, researchers have identified an increased homocysteine level in the blood (hyperhomocysteinemia) as an additional and independent risk factor for arteriosclerosis and coronary heart diseases. Similarly, hyperhomocysteinemia is linked with repeatedly occurring venous thromboses and apoplexy strokes.

9. Studies have shown that a combination of vitamins B₆, B₁₂, and folic acid can lower homocysteine levels in most patients. Thus, doctors increasingly recommend that their

patients with elevated homocysteine levels take supplements of vitamin B₆, vitamin B₁₂, and especially folic acid.

10. Several years ago, Plaintiff PamLab noted the medical interest in treating elevated homocysteine levels with vitamin B₁₂ and folic acid (also known as folate), and decided to formulate a product having these vitamins in suitable quantities. During the development of this product, PamLab discovered the groundbreaking work of two hematology professors at the University of Colorado School of Medicine, Dr. Robert H. Allen and Dr. Sally P. Stabler.

11. Drs. Allen and Stabler have devoted their careers to studying vitamin B₁₂ and folate. Their clinical work has been at the forefront of the research examining the relationship between those vitamins and homocysteine. Their studies have been widely cited and published in prestigious scientific journals such as the New England Journal of Medicine, and they have also been awarded several United States patents.

12. Among these is United States Patent No. 6,528,496, entitled “Compositions treating, preventing, or reducing elevated metabolic levels” (“the ’496 Patent”), which was duly and legally issued to Drs. Allen and Stabler on March 4, 2003. The ’496 Patent is attached as Exhibit A. The patent application that resulted in the issue of the ’496 Patent was a continuation application that claimed priority (through prior continuation and divisional applications) to a filing date of December 29, 1992.

13. Dr. Allen formed Metabolite Laboratories, Inc. (“Metabolite”) under the University of Colorado’s guidelines. The patents and applications leading to the ’496 Patent, and later the ’496 Patent itself, were assigned to Metabolite.

14. Accordingly, PamLab approached Metabolite in 1999 and began discussions concerning a patent license for certain products. PamLab first launched the product at issue in the

fall of 1999, while these discussions were in progress. Then on January 11, 2000, PamLab entered into a license agreement with Metabolite (the “Patent License”), under which Metabolite granted PamLab a license to certain formulations under several related patents and applications (one of which, through a subsequent continuation application, issued as the ’496 Patent), and PamLab agreed to pay Metabolite a royalty. Moreover, under the Patent License (as amended), PamLab has the right to enforce the ’496 Patent.

PamLab’s Prescription Product Foltx[®]

15. Pursuant to the Patent License, PamLab manufactures and sells a product with the trademarked name of “Foltx[®].”

16. Foltx[®] is available only by prescription from a licensed physician or other healthcare professional qualified to write prescriptions.

17. Foltx[®] contains three active ingredients, namely vitamin B₁₂, vitamin B₆, and folic acid. When Foltx[®] was first marketed by PamLab in October, 1999, it contained 1 mg. of vitamin B₁₂, 25 mg. of vitamin B₆, and 2.5 mg. of folic acid (the “1 mg. Foltx[®]”). Beginning in June, 2004, PamLab introduced Foltx[®] containing 2 mg. of vitamin B₁₂ instead of 1 mg. (“Improved Foltx[®]”). At the same time, PamLab discontinued all sales of the 1 mg. Foltx[®].

18. Since the time that PamLab launched Foltx[®] in October, 1999, the market for this product has grown steadily as physicians increasingly recognize the relationship between B₁₂ and folate and elevated homocysteine.

19. Much of this recognition is attributable to the huge investment in education that PamLab has undertaken. PamLab has spent millions of dollars calling on tens of thousands of physicians through PamLab’s sales force, providing millions of product samples, publishing articles and advertisements in medical journals, and funding additional clinical studies.

20. PamLab markets Foltx[®] directly to physicians as a medical food prescription product intended for the specific dietary management of individuals under a physician's treatment for hyperhomo-cysteinemia, with particular emphasis on individuals with or at risk for atherosclerotic vascular disease in the coronary, peripheral, or cerebral vessels, or individuals with vitamin B₁₂ deficiency.

Defendants' Infringing "Folnate" Products

21. In approximately September or October, 2007, Defendants launched the following new products which, according to their product labeling, contain active ingredients as follows:

- (a) Folnate: 1 mg. of vitamin B₁₂, 25 mg. of vitamin B₆, and 2.5 mg. folic acid; and
- (b) Folnate Plus: 2 mg. of vitamin B₁₂, 25 mg. of vitamin B₆, and 2.5 mg. of folic acid.

22. These two products (collectively, the "Folnate Products") are manufactured for Cura by defendant Andapharm, a contract manufacturer of pharmaceutical products, and are sold and distributed for Cura by defendant Bi-Coastal, a contract broker of such products.

23. Cura and Bi-Coastal, with Andapharm's knowledge and assistance, explicitly or implicitly represent that the Folnate Products are substitutable for Foltx[®].

24. Upon information and belief, Defendants have not scientifically determined whether the Folnate Products are substitutable for Foltx[®].

25. Moreover, upon information and belief, Cura and Bi-Coastal fail to distinguish between 1 mg. Foltx[®] and Improved Foltx[®], encouraging Folnate to be substituted for Improved Foltx[®].

26. Accordingly, by reason of the representations made by Cura and Bi-Coastal, with Andapharm's knowledge and assistance, that the Folnate Products are substitutable for Foltx[®],

purchases of one or more of the Folnate Products have been substituted for purchases of PamLab's Foltx[®].

COUNT I
Patent Infringement By All Defendants

27. PamLab incorporates the allegations of the preceding paragraphs as though fully set forth herein.

28. By manufacturing, marketing, selling, and offering to sell Folnate Plus, Defendants directly infringe, contributorily infringe, and/or induce infringement of, the '496 Patent.

29. PamLab has been injured thereby, in an amount to be determined at trial.

30. Upon information and belief, Defendants will continue their infringement of the '496 Patent unless their acts of infringement are restrained and enjoined by this Court. Should Defendants be permitted to continue their acts of infringement of the '496 Patent, PamLab will suffer irreparable injury for which it has no adequate remedy at law.

COUNT II
Violation Of The Lanham Act By Cura And Bi-Coastal

31. PamLab incorporates the allegations of the preceding paragraphs as though fully set forth herein.

32. Upon information and belief, because Defendants have not scientifically determined whether the Folnate Products are substitutable for Foltx[®], the explicit or implied representations made by Defendants that the Folnate Products are substitutable for Foltx[®] constitute false advertising under section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

33. PamLab has been injured thereby, in an amount to be determined at trial.

34. Upon information and belief, Defendants will continue their violation of the Lanham Act unless such violations thereof are restrained and enjoined by this Court. Should Defendants be permitted to continue their false advertising, PamLab will suffer irreparable injury for which it has no adequate remedy at law.

WHEREFORE, PamLab requests that the Court:

(a) Preliminarily and permanently enjoin Defendants, their officers, directors, employees, partners, agents, licensees, servants, successors and assigns, and any and all persons acting in privity or concert with them, from making, using, offering to sell, or selling the Folate Products;

(b) Enter judgment against Defendants for compensatory damages by reason of their infringement of the '496 Patent, as determined at trial, but not less than a reasonable royalty;

(c) Declare this case to be "exceptional" within the meaning of 35 U.S.C. § 285, entitling PamLab to an award of its reasonable attorneys fees, expenses and costs of this action;

(d) Preliminarily and permanently enjoin Defendants, their officers, directors, employees, partners, agents, licensees, servants, successors and assigns, and any and all persons acting in privity or concert with them, from representing that the Folate Products are substitutable for Foltx[®];

(e) Enter judgment against Defendants for compensatory damages by reason of their violation of the Lanham Act, as determined at trial; and

(f) Enter an Order granting PamLab such other and additional relief against Defendants as may be just and proper in the circumstances.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, PamLab demands a trial by jury of all issues properly triable to a jury in this case.

Dated: December 7, 2007

s/Michael R. Henson

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