

UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

PAMLAB, L.L.C.,  
METABOLITE LABORATORIES, INC., and  
BRECKENRIDGE PHARMACEUTICAL,  
INC.,

Plaintiffs,

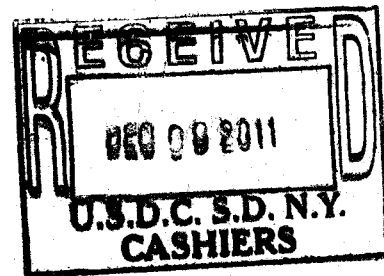
v.

MACOVEN PHARMACEUTICALS, L.L.C.,

Defendant.

**11 CIV 9022**  
Civil Action No. \_\_\_\_\_

**JURY TRIAL DEMANDED**



**COMPLAINT**

Plaintiffs Pamlab, L.L.C., Metabolite Laboratories, Inc., and Breckenridge  
Pharmaceutical, Inc., by and through their attorneys, state as follows for their Complaint against  
Defendant Macoven Pharmaceuticals, L.L.C.:

**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. Plaintiff Metabolite Laboratories, Inc. ("Metabolite") is a corporation existing  
under the laws of the State of Colorado, with its principal place of business at 301 Garfield  
Street, Unit 2-West, Denver, Colorado, 80206.

3. Plaintiff Breckenridge Pharmaceutical, Inc. ("Breckenridge") is a corporation existing under the laws of the State of Florida, with its principal place of business at 1141 South Rogers Circle, Suite 3, Boca Raton, Florida, 33487.

4. Defendant Macoven Pharmaceuticals, L.L.C. ("Macoven") is a Louisiana limited liability company with its principal place of business at 33219 Forest West Drive, Magnolia, Texas, 77354.

### **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 violations 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. Upon information and belief, Macoven is subject to personal jurisdiction in this district because it markets and sells products to nationwide retail drug store chains, including those with locations within this judicial district, as well as through nationwide distributors and databases that target this judicial district.

### **STATEMENT OF FACTS**

#### **The Research Leading to the Patent in Suit and PamLab's 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, B<sub>6</sub> and B<sub>12</sub>, 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 B<sub>6</sub>, B<sub>12</sub>, 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 B<sub>6</sub>, vitamin B<sub>12</sub>, and especially folic acid.

10. Some years ago, Plaintiff PamLab noted the medical interest in treating elevated homocysteine levels with vitamin B<sub>12</sub>, vitamin B<sub>6</sub>, 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 B<sub>12</sub>, vitamin B<sub>6</sub>, 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 a number of 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.

13. Dr. Allen formed Plaintiff 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, so that Metabolite is the owner of all right, title, and interest in the '496 Patent, as well as the related patents.

14. Accordingly, PamLab approached Metabolite in 1999 and began discussions concerning a patent license for certain products. PamLab first launched the product at issue (as discussed hereinafter) 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 an exclusive license to certain formulations under several related patents and applications (one of which, through a subsequent continuation application, issued as the '496 Patent). Moreover, under the Patent License (as amended), PamLab has the right to enforce the '496 Patent.

**PamLab's Licensed Product Foltx<sup>®</sup>**

15. Pursuant to the Patent License, PamLab manufactures and sells a product with the trademarked name of "Foltx<sup>®</sup>." PamLab pays Metabolite a royalty based on the value of the sales of Foltx<sup>®</sup>.

16. Foltx<sup>®</sup> is marketed to licensed physicians and other healthcare professionals.

17. Foltx<sup>®</sup> contains three active ingredients, namely vitamin B<sub>12</sub>, vitamin B<sub>6</sub>, and folic acid. When Foltx<sup>®</sup> was first marketed by PamLab in October, 1999, it contained 1 mg. of vitamin B<sub>12</sub>, 25 mg. of vitamin B<sub>6</sub>, and 2.5 mg. of folic acid. Beginning in June, 2004, PamLab introduced Foltx<sup>®</sup> containing 2 mg. of vitamin B<sub>12</sub> instead of 1 mg., and discontinued sales of the 1 mg. Foltx<sup>®</sup>.

18. After PamLab launched Foltx<sup>®</sup> in October, 1999, the market for this product grew steadily as physicians increasingly recognized the relationship between elevated homocysteine and vitamin B<sub>12</sub>, vitamin B<sub>6</sub>, and folate.

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<sup>®</sup> to physicians as a medical food product intended for the specific dietary management of individuals under a physician's treatment for hyperhomocysteinemia, with particular emphasis on individuals with or at risk for atherosclerotic vascular disease in the coronary, peripheral, or cerebral vessels, or individuals with vitamin B<sub>12</sub> deficiency.

**Breckenridge's Patent Sublicense and Its Licensed Folic Acid Products**

21. In 2007, Breckenridge entered into a patent sublicense with PamLab under a number of the Metabolite patents, with the express consent of Metabolite, including but not limited to the '496 Patent, and including the right to enforce the '496 Patent. This agreement also provides Breckenridge with additional rights to be the exclusive marketer of generic versions of the PamLab products identified therein.

22. Under this agreement, Breckenridge now markets the only licensed generic version of Foltx<sup>®</sup>. Breckenridge markets a product containing 2 mg. of vitamin B<sub>12</sub>, 25 mg. of vitamin B<sub>6</sub>, and 2.5 mg. of folic acid as "Folbic<sup>®</sup>".

23. Breckenridge pays a royalty to PamLab pursuant to the sublicense, which in turn pays a royalty to Metabolite.

**Macoven's Folic Acid Product**

24. Upon information and belief, Macoven has manufactured or had manufactured, for sale in the United States, a product which Macoven represents to contain 2 mg. of vitamin

B<sub>12</sub>, 25 mg. of vitamin B<sub>6</sub>, and 2.5 mg. of folic acid (“Macoven’s Folic Acid Product”), the same active ingredients in the same amounts as Foltx<sup>®</sup> and Folbic<sup>®</sup>.

25. Upon information and belief, Macoven either directly represents that its Folic Acid Product contains these amounts of these active ingredients, or made such representations as were necessary to cause one or more industry databases to represent to the industry that Macoven’s Folic Acid Product contains 2 mg. of vitamin B<sub>12</sub>, 25 mg. of vitamin B<sub>6</sub>, and 2.5 mg. of folic acid.

26. Macoven has offered Macoven’s Folic Acid Product for sale in commerce in the United States.

27. Upon information and belief, in offering its Folic Acid Product for sale, Macoven has represented, explicitly or implicitly, that its Folic Acid Product is substitutable for Foltx<sup>®</sup> and/or Folbic<sup>®</sup>.

28. Upon information and belief, Macoven has not scientifically determined whether its Folic Acid Product is substitutable for Foltx<sup>®</sup> and/or Folbic<sup>®</sup>.

**COUNT I**  
**Patent Infringement**

29. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

30. By manufacturing, selling, and/or offering to sell its Folic Acid Product, Macoven has infringed and is infringing the ’496 Patent under 35 U.S.C. section 271(a), literally and/or under the doctrine of equivalents, and/or by having its Folic Acid Product manufactured to contain the active ingredients as specified above, with knowledge that its Folic Acid Product would infringe the ’496 Patent, Macoven has induced infringement of and/or contributed to the infringement of the ’496 Patent under 35 U.S.C. section 271 (b) and/or (c).

31. Plaintiffs have been injured thereby, in an amount to be determined at trial.

32. Upon information and belief, the infringement of the '496 Patent by Macoven has been and is willful.

33. Upon information and belief, Macoven will continue its infringement of the '496 Patent unless its acts of infringement are restrained and enjoined by this Court. Should Macoven be permitted to continue its acts of infringement of the '496 Patent, Plaintiffs will suffer irreparable injury for which they have no adequate remedy at law.

**COUNT II**  
**Violation Of The Lanham Act**

34. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

35. In the alternative, if Macoven does not infringe the '496 Patent, either literally or under the doctrine of equivalents, or contribute to and/or induce the infringement of the '496 Patent, then Macoven has misrepresented the active ingredients contained in its Folic Acid Product, which constitutes false and/or misleading descriptions and representations of fact that misrepresent the nature, characteristics, and/or qualities of Macoven's Folic Acid Product, and otherwise constitutes false advertising under section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

36. In addition, upon information and belief, because Macoven has not scientifically determined whether Macoven's Folic Acid Product is substitutable for Foltx<sup>®</sup> and/or Folbic<sup>®</sup>, the explicit or implied representations by Macoven, in commerce, that its Folic Acid Product is substitutable for Foltx<sup>®</sup> and/or Folbic<sup>®</sup> are false and/or misleading descriptions and representations of fact that misrepresent the nature, characteristics, and/or qualities of Macoven's Folic Acid Product, and otherwise constitute false advertising in violation of section 43(a) of the

Lanham Act, 15 U.S.C. § 1125(a).

37. Plaintiffs have been and/or will be injured thereby, in an amount to be determined at trial.

38. Upon information and belief, Macoven will continue its violations of the Lanham Act unless such acts are restrained and enjoined by this Court. Should Macoven be permitted to continue its false and/or misleading descriptions and representations of fact and false advertising, Plaintiffs will suffer irreparable injury for which they have no adequate remedy at law.

**WHEREFORE**, Plaintiffs request that the Court:

(a) Preliminarily and permanently enjoin Macoven, its officers, directors, employees, partners, agents, licensees, servants, successors and assigns, and any and all persons acting in privity or concert with them, from making, having made, using, offering to sell, or selling Macoven's Folic Acid Product;

(b) Enter judgment against Macoven for compensatory damages by reason of its infringement of the '496 Patent, as determined at trial, but not less than a reasonable royalty, in an amount to be determined at trial;

(c) Determine that such infringement was willful, and award treble damages to Plaintiffs by reason thereof;

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

(e) Preliminarily and permanently enjoin Macoven, its officers, directors, employees, partners, agents, licensees, servants, successors and assigns, and any and all persons acting in



privity or concert with them, from representing, explicitly or implicitly, that Macoven's Folic Acid Product is substitutable for Foltx<sup>®</sup> and/or Folbic<sup>®</sup>;

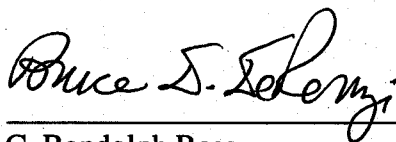
(f) Enter judgment against Macoven for compensatory damages by reason of its violation of the Lanham Act, as determined at trial, in an amount to be determined at trial; and

(g) Enter an Order granting Plaintiffs such other and additional relief against Macoven 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, Plaintiffs demand a trial by jury of all issues properly triable to a jury in this case.

Dated: New York, New York  
December 9, 2011



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