UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

PAMLAB, L.L.C., METABOLITE LABORATORIES, INC., and BRECKENRIDGE PHARMACEUTICAL, INC., Plaintiffs, v. VIVA PHARMACEUTICAL, INC., Defendant.	Case No. _____ **COMPLAINT FOR PATENT INFRINGEMENT AND LANHAM ACT VIOLATIONS** **JURY TRIAL DEMANDED**

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 Viva Pharmaceutical, Inc.:

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.

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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 1133 14th Street, Unit 3600, Denver, Colorado 80202.

3. 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 Viva Pharmaceutical, Inc. ("Viva") is a corporation existing under the laws of British Columbia, Canada, with its principal place of business at 13880 Viking Place, Richmond, British Columbia, V6V 1K8, Canada, which is in the process of constructing a facility in Blaine, Washington.

5. Viva manufactures numerous pharmaceutical products for sale in the United States, works in partnership with companies in the United States in the development of these products, decides on the ingredients and manufacturing specifications in cooperation with companies in the United States, determines or confirms the expiration date to be assigned to its products sold in the United States, and ships those products to the United States for sale in the United States. Viva also owns at least three United States patents and is prosecuting a number of applications for additional United States patents.

Jurisdiction And Venue

6. 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.

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7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1400 and 1391. Upon information and belief, Viva is subject to personal jurisdiction in this district because it has systematic and continuous contacts in this district, and because it manufactures products that are sold and shipped 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, and it has purposefully availed itself of the Washington market.

STATEMENT OF FACTS

The Research Leading to the Patent in Suit and Pamlab's Patent License

8. 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_6 and B_{12}, the concentration of homocysteine in the blood and urine increases.

9. 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.

10. Studies have shown that a combination of vitamins B_6, B_{12}, 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_6, vitamin B_{12}, and especially folic acid.

11. Some years ago, Plaintiff Pamlab noted the medical interest in treating elevated homocysteine levels with vitamin B_{12}, vitamin B_6, and folic acid (also known as folate), and decided to formulate a product having these vitamins in suitable quantities. During the

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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.

12. Drs. Allen and Stabler have devoted their careers to studying vitamin B_{12}, vitamin B_6, 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.

13. 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.

14. 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.

15. 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 an exclusive license to certain formulations under several related patents and applications (one of which, through a subsequent continuation application, issued as the '496

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Patent). Moreover, under the Patent License (as amended), Pamlab has the right to enforce the '496 Patent.

Pamlab's Licensed Product Foltx®

16. Pursuant to the Patent License, Pamlab manufactures and sells a product with the trademarked name of "Foltx®." Pamlab pays Metabolite a royalty based on the value of the sales of Foltx®.

17. Foltx® is marketed to licensed physicians and other healthcare professionals.

18. Foltx® contains three active ingredients, namely 2 mg. of vitamin B_{12}, 25 mg. of vitamin B_6, and 2.5 mg. of folic acid.

19. After Pamlab launched Foltx® in October, 1999, the market for this product grew steadily as physicians increasingly recognized the relationship between elevated homocysteine and vitamin B_{12}, vitamin B_6, and folate.

20. Much of this recognition is attributable to the huge investment in education that Pamlab has undertaken. Pamlab 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.

21. Pamlab marketed Foltx® 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_{12} deficiency.

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Breckenridge's Patent Sublicense and Its Licensed Folic Acid Products

22. 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.

23. Under this agreement, Breckenridge now markets the only licensed generic version of Foltx®. Breckenridge markets a product containing 2 mg. of vitamin B_{12}, 25 mg. of vitamin B_6, and 2.5 mg. of folic acid as "Folbic®".

24. Breckenridge pays a royalty to Pamlab pursuant to the sublicense, which in turn pays a royalty to Metabolite.

Viva's Folic Acid Product

25. Upon information and belief, Viva has manufactured, for sale in the United States by Macoven Pharmaceuticals, L.L.C. ("Macoven"), a product which it knew would be marketed by Macoven as containing 2.5 mg. of folic acid, 2 mg. of vitamin B_{12}, and 25 mg. of vitamin B_6 ("Viva's Folic Acid Product").

26. Viva knew from its own experience in prior litigation that these were the same active ingredients in the same amounts as in Foltx® and Folbic®, and that Macoven would market this product as substitutable for Foltx® and Folbic®.

27. Macoven has been representing to prospective purchasers of Viva's Folic Acid Products, who are also customers of Pamlab and Breckenridge, that its product in fact contains the same active ingredients as, and can be substituted for, Foltx® and Folbic®. In the

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pharmaceutical industry, such representations are understood to mean that Macoven's manufacturer has supplied Macoven with suitable and sufficient testing data, in the form of a "certificate of analysis," to establish that each active ingredients is present (and is available to the end consumer) in the amount stated on the product label.

28. Upon information and belief, Viva, as an established participant in the United States pharmaceutical market, is well aware of this industry standard and understanding, and yet participated in a sham by providing to Macoven what purported to be a standard certificate of analysis, but which in fact only provided test results for one of the three active ingredients.

29. Moreover, upon information and belief, Viva is aware of the regulations governing the manufacture of dietary supplements, and of the current Good Manufacturing Practices ("cGMPs") incorporated into federal regulations, including the requirements for testing contained in 21 C.F.R. § 111.75. These cGMPs form part of the regulatory context that would lead purchasers in the United States pharmaceutical industry to believe that Macoven's representations of the active ingredients in Viva's Folic Acid Product were supported by adequate testing, whereas, upon information and belief, Viva had provided Macoven with a "certificate of analysis" not supported by actual testing for two of the three active ingredients.

30. In addition, Viva supported and authorized affixing an expiration date to its Folic Acid Product, which was necessary to enable this product to compete with Plaintiffs' products. The assignment of an expiration date to a pharmaceutical product is understood in the pharmaceutical industry as a representation that appropriate stability testing has been performed, and that the results of such testing support that expiration date.

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31. Therefore, the marketing of Viva's Folic Acid Product with an expiration date stamped on the package labels represents and advertises to the mutual purchasers of Plaintiffs' products and Viva's Folic Acid Product that stability testing sufficient to justify these expiration dates had been performed.

32. However, upon information and belief, stability testing was not performed, and has not yet been performed, for at least one of the three active ingredients, making such an expiration date for Viva's product unsupported by the data.

33. Upon information and belief, Viva has participated in, or made on its own, other additional false and/or misleading descriptions and representations of fact, in commerce, that misrepresent the nature, characteristics, and/or qualities of its Folic Acid Product.

COUNT I
Patent Infringement

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

35. By shipping its Folic Acid Product to be sold in the United States, Viva has infringed the '496 Patent under 35 U.S.C. section 271(a), and/or, by the above conduct, with both knowledge and intent that its Folic Acid Product would infringe the '496 Patent, Viva 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).

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

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

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38. Upon information and belief, Viva will continue its acts of direct and indirect infringement of the '496 Patent unless such acts are restrained and enjoined by this Court. Should Viva 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

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

40. Upon information and belief, Viva participated in and contributed to the implicit and/or explicit representations by Macoven that adequate testing had been conducted on Viva's Folic Acid Product to confirm that it contains the same active ingredients in the same amounts as Foltx® and/or Folbic®, and/or that it is substitutable for Foltx® and/or Folbic®, and Viva has made or participated in other explicit and/or implicit representations, which constitute false and/or misleading descriptions and representations of fact, in commerce, that misrepresent the nature, characteristics, and/or qualities of Viva's Folic Acid Product, in violation of section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

41. In addition, the marketing of Viva's Folic Acid Product with an expiration date stamped on the package labels, upon information and belief as authorized and directed by Viva, also constitutes false and/or misleading descriptions and representations of fact, in commerce, that misrepresent the nature, characteristics, and/or qualities of Viva's Folic Acid Product, in violation of section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

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

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43. Upon information and belief, Viva will continue its violations of the Lanham Act unless such violations thereof are restrained and enjoined by this Court. Should Viva be permitted to continue its false and 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) Permanently enjoin Viva, 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, using, offering to sell, or selling in the United States, or importing into the United States, its Folic Acid Product;

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

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

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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 this 17th day of January, 2012.

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