JUDGE WOOD 10 CV 7078

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

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

Plaintiffs,

v.

ALLEGIS PHARMACEUTICAL, L.L.C.,

Defendant.

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 Allegis Pharmaceutical, 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. 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. Upon information and belief, defendant Allegis Pharmaceutical, L.L.C. ("Allegis") is a limited liability company existing under the laws of the State of Mississippi, with its principal place of business at 276 Nissan Drive, Suite B-2, Canton, Mississippi, 39046.

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. On information and belief, Allegis 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_6 and B_{12}, 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_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.

10. Several 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 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_{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.

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®

15. 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®.

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

17. Foltx® contains three active ingredients, namely vitamin B_{12}, vitamin B_6, and folic acid. When Foltx® was first marketed by Pamlab in October, 1999, it contained 1 mg. of vitamin B_{12}, 25 mg. of vitamin B_6, and 2.5 mg. of folic acid (the "1 mg. Foltx®"). Beginning in June, 2004, Pamlab introduced Foltx® containing 2 mg. of vitamin B_{12} instead of 1 mg. (the "2 mg. Foltx®"), and discontinued sales of the 1 mg. Foltx®.

18. 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.

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® 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.

Breckenridge's Patent Sublicense and Its Licensed Folic Acid Products

21. Several years ago, Breckenridge also began marketing a product containing 1 mg. of vitamin B_{12}, 25 mg. of vitamin B_6, and 2.5 mg. of folic acid ("Folbee®"), and later introduced a product containing 2 mg. of vitamin B_{12} instead of 1 mg. ("Folbic™").

22. In late 2004, a series of lawsuits in several jurisdictions commenced between Metabolite and Pamlab, on the one hand, and Breckenridge on the other. In 2007 the three plaintiffs resolved their disputes with a final settlement, pursuant to which Breckenridge entered into a patent sublicense with Pamlab under a number of the Metabolite patents.

23. Accordingly, under the patent sublicense, Breckenridge now markets the only licensed generic versions of both the 1 mg. Foltx® and the 2 mg. Foltx®, still under the names of

Folbee® and Folbic™. Breckenridge pays a royalty to Pamlab pursuant to the sublicense, which in turn pays a royalty to Metabolite.

The Allegis Folic Acid Products

24. Upon information and belief, Allegis has offered for sale in the United States two separate products which combine folic acid, vitamin B_{12} and vitamin B_6 (collectively, the "Allegis Folic Acid Products"). Upon information and belief, Allegis represents that one of these products contains 1 mg. of vitamin B_{12}, 25 mg. of vitamin B_6, and 2.5 mg. folic acid (the "1 mg. Allegis Folic Acid Product"), the same active ingredients as 1 mg. Foltx® and Folbee®.

25. Upon information and belief, Allegis represents that the other of these products contains 2 mg. of vitamin B_{12}, 25 mg. of vitamin B_6, and 2.5 mg. of folic acid (the "2 mg. Allegis Folic Acid Product"), the same active ingredients as 2 mg. Foltx® and Folbic™.

26. Upon information and belief, in offering the Allegis Folic Acid Products for sale, Allegis has explicitly or implicitly represented that both of these products are substitutable for Foltx®, Folbee®, and/or Folbic™.

27. Upon information and belief, Allegis has not scientifically determined whether its Folic Acid Products are substitutable for Foltx®, Folbee®, and/or Folbic™.

COUNT I
Patent Infringement

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

29. By manufacturing, marketing, selling, and offering to sell its 2 mg. Folic Acid Product, Allegis has infringed and is infringing the '496 Patent.

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

31. Upon information and belief, the infringement of the '496 Patent by Allegis is willful.

32. Upon information and belief, Allegis will continue its infringement of the '496 Patent unless its acts infringement are restrained and enjoined by this Court. Should Allegis 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

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

34. Upon information and belief, because Allegis has not scientifically determined whether the Allegis Folic Acid Product claiming to contain 2 mg. of vitamin B_{12} is substitutable for 2 mg. Foltx®, and/or Folbic™, and/or because the Allegis Folic Acid Product that claims to contain only 1 mg. of vitamin B_{12} cannot be substituted therefor; and because Allegis has not scientifically determined whether the Allegis Folic Acid Product claiming to contain 1 mg. of vitamin B_{12} is substitutable for Folbee®; therefore, the explicit or implied representations made by Allegis, in commerce, that its Folic Acid Products are substitutable for any of the above products are false and/or misleading descriptions that misrepresent the nature, characteristics, and/or qualities of its Folic Acid Products, and thus constitute false advertising under section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

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

36. Upon information and belief, Allegis will continue its violation of the Lanham Act unless such violations thereof are restrained and enjoined by this Court. Should Allegis be

permitted to continue its 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 Allegis, 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 the Allegis Folic Acid Products;

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

(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 Allegis, 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 that the Allegis Folic Acid Products are substitutable for Foltx®, Folbee®, and/or Folbic™;

(f) Enter judgment against Allegis for compensatory damages by reason of its violation of the Lanham Act, as determined at trial; and

(g) Enter an Order granting Plaintiffs such other and additional relief against Allegis 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.

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