

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

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|---|---|------------------------------|
| PAMLAB, L.L.C., |) | CIVIL ACTION NO. 2:11- _____ |
| |) | |
| Plaintiff, |) | SECTION ____ |
| |) | |
| v. |) | MAGISTRATE DIVISION ____ |
| |) | |
| ACELLA PHARMACEUTICALS, LLC, ARIZONA |) | JURY DEMANDED |
| NUTRITIONAL SUPPLEMENTS, INC., ULTIMATE |) | |
| FORMULATIONS, INC. d/b/a BEST |) | |
| FORMULATIONS, LIANYUNGANG JINKANG |) | |
| PHARMACEUTICAL TECHNOLOGY CO., LTD., |) | |
| MARK W. PUGH AND HAROLD A. DEAS, JR., |) | |
| |) | |
| Defendants. |) | |

ORIGINAL COMPLAINT

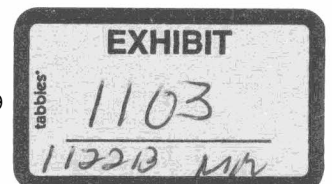
Plaintiff PamLab, L.L.C. ("PamLab") files this Complaint against Defendants Acella Pharmaceuticals, LLC ("Acella"), Arizona Nutritional Supplements, Inc. ("Arizona"), Ultimate Formulations, Inc. d/b/a Best Formulations ("Best"), Lianyungang Jinkang Pharmaceutical Technology Co., Ltd. ("LJ Pharma"); Mark W. Pugh ("Pugh") and Harold A. Deas, Jr. ("Deas") (collectively, "Defendants") and allege as follows:

1. This action arises out of Defendants' knowing and willful false and misleading advertising and promotion of their pharmaceutical products. Defendants' actions constitute false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); federal unfair competition in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A); violation of 51:1405(A) of the Louisiana Unfair Trade Practices and Consumer Protection Law; and unfair competition and misappropriation in violation of Louisiana common law. Plaintiff seeks temporary, preliminary and permanent injunctive relief; actual damages; punitive damages; and recovery of Plaintiff's costs and reasonable attorneys' fees incurred in connection with this action.

Gnosis Ex. 1103

Gnosis v. Merck/SAMSF

-¹ IPR2013-116, -117, -118, -119



and has proven to have a high degree of bioavailability (the rate at which a drug or other substance is available at the targeted place in the body) in humans. In contrast, the D-form is an unnatural form of folate, from which humans are unable to obtain nutritional benefit.

25. L-methylfolate is the pure diastereoisomeric form of folate used by cells in the body. In humans, this particular compound is the predominant form in circulation and transport into the tissues, and it is the only folate that can cross the blood-brain barrier.

26. While the D-form is useless as a source of folate nutrition, it is not inert. For example, scientific evidence shows that the unnatural D-form accumulates in the human body. Further, the evidence suggests that the D-methylfolate diastereoisomer competes with the body's uptake of the L-methylfolate diastereoisomer and therefore reduce the overall usability of the compound.

27. In the mid-1990's, Merck & Cie (formerly known as Merck Eprova AG) ("Merck") made a key breakthrough, and invented a process to synthesize L-methylfolate in a stable form. Offered under the name Metafolin[®] (METAFOLIN), L-methylfolate calcium¹ is the crystalline, stable and diastereoisomerically pure form of folate directly usable by cells in the body.

28. L-methylfolate calcium is defined throughout the world in compendial standards and submissions to government agencies – including the FDA – as a substantially diastereoisomerically pure dietary ingredient which has 1% or less of the D-methylfolate isomer. Each batch of METAFOLIN is tested by Merck to ensure that it meets these standards.

29. METAFOLIN is protected by a comprehensive set of patents and patent applications on the substance, key intermediates, production processes and its use in specific

¹ The terms L-methylfolate and L-methylfolate calcium will be used interchangeably. Although the ingredient used in the manufacture of the PAMLAB PRODUCTS is accurately termed L-methylfolate calcium, once ingested, the calcium ion dissociates from the L-methylfolate molecule, leaving L-methylfolate as a free acid. The free acid form of L-methylfolate is the active component of the molecule in the human body.