

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff,

v.

ENZYMATIC THERAPY, INC., a
corporation; BIO-THERAPEUTICS,
LTD., a corporation; LEM'S CONTRACT
PRINTING, INC. (a.k.a. "Lem's Printing
Shop," "Vital Communications, Inc.,"
and "Lee's Contract Printing"), a
corporation; TERRENCE J. LEMEROND,
individually and doing business as BAY
NATURAL FOODS; and BRADLEY LEMEROND,
an individual,

Case 91-C-117

Defendants.

COMPLAINT FOR INJUNCTION

Plaintiff, the United States of America, by John E. Fryatt,
United States Attorney for the Eastern District of Wisconsin,
respectfully represents to this Honorable Court as follows:

1. This statutory injunction proceeding is brought pursuant
to the Federal Food, Drug, and Cosmetic Act (the "FDC Act"), 21
U.S.C. § 332(a), which vests the district courts of the United
States with jurisdiction to enjoin and restrain violations of the
FDC Act.

2. This Court has jurisdiction over this action pursuant to
28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332(a). Venue
in the Eastern District of Wisconsin is proper pursuant to 28
U.S.C. § 1391(b) and (c).

3. Defendant Enzymatic Therapy, Inc. is a Wisconsin corporation doing business at 510 Lombardi Avenue, Green Bay, Wisconsin, within the jurisdiction of this Court.

4. Defendant Bio-Therapeutics, Ltd. is a Wisconsin corporation doing business at 510 Lombardi Avenue, Green Bay, Wisconsin, within the jurisdiction of this Court.

5. Defendant Lem's Contract Printing (a.k.a "Lem's Printing Shop," "Vital Communications," and "Lee's Contract Printing") is a Wisconsin corporation doing business at 300 South Quincy Street, Green Bay, Wisconsin, within the jurisdiction of this Court.

6. Defendant Terrence J. Lemerond, an individual, is the president of defendants Enzymatic Therapy, Inc. and Bio-Therapeutics, Ltd. He is the person most responsible for the operations of the aforementioned defendant corporations. He also is the proprietor of and does business as Bay Natural Foods, which is located at 722 Bodart Street, Green Bay, Wisconsin, within the jurisdiction of this Court. Mr. Lemerond resides at 2831 Viking Drive, Green Bay, Wisconsin, also within the jurisdiction of this Court.

7. The defendant Bradley Lemerond, an individual, is the president of Lem's Contract Printing, Inc. He is the person most responsible for the operations of that corporation.

8. The defendants have been and are now engaged, at their facilities in Green Bay, Wisconsin, in manufacturing, packing, processing, distributing, selling, promoting, labeling, and

advertising a number of products about which they make, directly and by implication, therapeutic claims. As a result of such claims, these products are drugs within the meaning of 21 U.S.C. § 321(g)(1)(B), because they are intended for use in the cure, mitigation, treatment, or prevention of disease in humans. Among the products for which defendants have made and are making therapeutic claims are the following:

- Artho-Flex No. 175/176
- Arthorex No. 1175
- Prostone No. 190
- Prost-Care No. 1190
- Herpilyn No. 265A
- HI-BP No. 275
- Vascu-Comp 1275
- Cardio-Tone No. 285
- Cardio-Plex No. 1285C
- Allerfree/Allernex No. 330
- Allerril No. 1330
- PMX No. 365
- Premens No. 1365
- Raw Pancreas Complex No. 400
- Raw Heart Complex No. 401A
- L-Carnitine Complex No. 1401A
- Immuno-Plex No. 402A
- Thymic Fractions No. 1402A
- Lung-Thymus Complex No. 409A
- Lung-Thymus Soluble Fractions No. 1409A
- Orchic-Prostate Complex No. 411-13A
- Thyroid Supplement No. 414B
- Thyro-Tone No. 1414B
- EPA-Cur No. 477
- Allisatin No. 504
- Candiplex No. 1504
- Herbal Cleanse No. 751
- Herbal Cleanse No. 1751
- Silymarin (7x) No. 800
- Hepa-Guard No. 1800
- Silymarin 80% No. 800 PSE
- Silymarin Complex No. 801 PSE
- Choleretic Complex NO. 1801
- Silymarin Phytosome No. 1802
- Artho-Comp No. 807 PSE
- Candizactin No. 1809A
- Kan-Kleer No. 809 PSE.
- Vasculex No. 813

Vascu-Tone No. 1813
Nico-Tabs No. 184 PSE
Nicoril No. 1814
Aller-Comp No. 824A
Echinacea Root No. 831B PSE
Echinocide No. 1831B
Prost-Ada No. 835 PSE
Prostaril No. 1835B
IBS No. 845 PSE
Entero-Pep No. 1845
Golden Seal Root Extract No. 853 PSE
Hydrastis No. 1853
Hypericin No. 864
Hypericin Plus No. 1864
Classic Formula C.A. No. 896
Echinacea Angustifolia No. 898
MVP Nos. 1 and 4
VRP Nos. 1 and 4

9. Typical and illustrative of the types of therapeutic claims that defendants have been making about their products are the following:

a. "HI/BP No. 275 . . . Natural Support for the body systems involved in maintaining healthy blood pressure."

b. "Artho-Comp No. 807 P.S.E. . . . Herbal support for healthy joint function."

c. "Those concerned about the level of Candida in the body may wish to support the systems that work to keep the yeast in check . . . Candiplex No. 1504 provides these powerful natural compounds in an enteric-coated tablet designed to deliver these nutrients to the intestines, where they can help re-establish a healthy colony of friendly bacteria."

d. "L-Carnitine Complex No. 1401A . . . Carnitine's ability to burn fatty acid also contributes to the body's natural control of blood sugar, cholesterol, and triglyceride levels."

e. "Echinacea angustifolia is remarkable in its ability to support the body's natural production of immune compounds . . . Studies now show echinacea's polysaccharides can bind directly to the surface of white blood cells, increasing interferon production and T-cell reproduction. Echinocide No. 1831B contains extract of echinacea standardized for its active principles for maximum natural benefits."

f. "Thymic Fractions No. 1402A contains an exclusive extract of nutrient-rich calf thymus tissue, combined with natural glandular factors, vitamins, minerals, enzymes, and herbs. This formula is designed to provide natural support to the function of the thymus gland, immune system, and lymph system."

g. "High-quality extracts of thymus tissue can help stimulate healthy thymic activity. . . Clinical trials show thymus extracts can provide powerful natural support for strong immune functions in children with respiratory infections or allergies, and individuals with hepatitis B, AIDS, or cancer."

10. Those products about which the defendants have been making therapeutic claims are "new drugs" within the meaning of 21 U.S.C. § 321(p) because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.

11. No approved new drug applications filed pursuant to 21 U.S.C. § 355(b) or (j) are in effect for the products about which defendants have been making therapeutic claims, nor are any of these products subject to an investigational new drug exemption in effect pursuant to 21 U.S.C. § 355(i) and regulation 21 C.F.R. § 312.40. Accordingly, pursuant to 21 U.S.C. § 355(a), these products may not be introduced lawfully into interstate commerce.

12. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce unapproved "new drugs."

13. The products about which defendants have been making therapeutic claims are also misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for their intended uses.

14. Defendants violate 21 U.S.C. § 331(a) by introducing and delivering for introduction into interstate commerce misbranded drugs.

15. Defendants have been notified and are aware that their activities violate the FDC Act. Between 1986 and the present, defendants Enzymatic Therapy and Terrence Lemerond received two letters from the Food and Drug Administration ("FDA") warning them that therapeutic claims in labeling and promotional materials accompanying products rendered those products misbranded and unapproved new drugs. In addition, in September 1989, defendant Terrence Lemerond and his attorney met with representatives of FDA and admitted that some of defendants'

products were being promoted and sold in violation of the FDC Act; they also promised to discontinue distribution of objectionable promotional materials and to submit revised labeling and promotional materials to FDA for review.

16. Despite the aforesaid efforts by FDA to bring defendants into compliance with the FDC Act, and despite promises from defendant Terrence Lemerond to bring defendants' products into compliance, defendants continue to promote, manufacture, and distribute misbranded and unapproved new drugs. Plaintiff is informed and believes that, unless restrained by this Honorable Court, defendants may well continue to violate 21 U.S.C. § 331(a), (d) in the manner alleged.

WHEREFORE, PLAINTIFF PRAYS THAT THIS COURT:

1. Enjoin defendants permanently from manufacturing, packing, processing, distributing, or selling misbranded or unapproved new drugs in violation of 21 U.S.C. § 331(a), (d); and

2. Award plaintiff the costs of bringing this action, as well as such other and additional relief as the Court may determine to be proper and just.

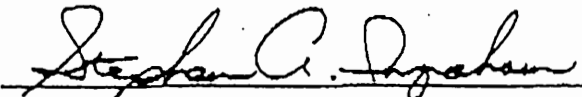
DATED this 13th day of ~~October~~ ^{November}, 1991.

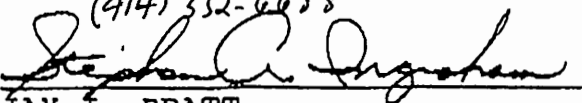
Respectfully submitted,

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