JUDGE SWEET

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

04 CV 08106

MK SYSTEMS, INC.,

Plaintiff,

-against-

DAVID SCHMIDT, LIFEWAVE PRODUCTS LLC,

Defendants.

CASE NO.

COMPLAINT

Plaintiff, MK SYSTEMS, INC., by its attorneys, Rubin Bailin Ortoli Mayer & Baker LLP, sets forth as its complaint against the Defendants as follows:

PARTIES

1. Plaintiff, MK SYSTEMS, INC., (hereinafter "Plaintiff") is a corporation incorporated under the laws of the State of * New York, having its principal place of business at 500 Fifth Avenue, in the City, County and State of New York.

2. Plaintiff is the exclusive distributor of certain LifeWave Products as hereinafter set forth.

3. Defendant LIFEWAVE LLC, (hereinafter "LIFEWAVE") is a Limited Liability Company existing under and by virtue of the laws of the State of Georgia, having its principal place of business at 1000 Peachtree Int Blvd, Suite 6-321, Suwanee, GA 30024.

4. Defendant, DAVID SCHMIDT, (hereinafter "SCHMIDT") is a member

of the Defendant LIFEWAVE, whose offices are located at 1000 Peachtree Int Blvd, Suite 6-321, Suwanee, GA 30024.

JURISDICTIONAL ALLEGATIONS

5. This Court has original jurisdiction under 28 U.S.C. § 1332, in that there is diversity of citizenship between the parties and the amount in controversy exceeds seventy five thousand dollars.

6. This Court has original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States pursuant to 28 U.S.C.A. § 1331, where a federal question is invoked.

7. This action concerns the Federal Food Drug and Cosmetic Act 21 U.S.C. CH. 9 *et seq.*, (hereinafter the "Act")

8. Venue is proper under 28 U.S.C.A. § 1391 as the judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, is the judicial district of this Court and the defendant is subject to personal jurisdiction of this Court.

9. The subject contract, as hereinafter alleged, was negotiated in the State of New York.

10. The subject contract, as hereinafter alleged, was executed in the State of New York.

11. The Defendants transact business within New York State.

12. The Defendants have contracted for, and continue to contract to supply goods in New York State.

13. The Defendants have committed a tortious act within the State of New York.

14. The Defendants have committed tortious acts without the State of New York, causing injury to persons within the State of New York.

15. The Defendants regularly do business in, solicit, and/or engage in other persistent courses of conduct, and/or derive substantial revenue from goods used or consumed in the State of New York.

16. The Defendants expect or should reasonably expect its actions to have consequences in the State of New York, and derive substantial revenue from interstate commerce.

ALLEGATIONS APPLICABLE TO ALL COUNTS

17. Between March and July of 2003 the Plaintiff by its President, Mark Kline, and the Defendant LIFEWAVE by its member and individual Defendant SCHMIDT, negotiated the terms by which Plaintiff would become the exclusive distributor of LIFEWAVE products, including the sports patches for strength and stamina

enhancement and pain relief, manufactured and supplied by Defendant LIFEWAVE, (hereinafter the "Products").

18. The foregoing negotiations resulted in the parties entering into a written contract entitled "Exclusively Agreement regarding LifeWave Technology Products," on July 10, 2003 (hereinafter the "Agreement").

19. Paragraph 2 of the Agreement provides for the exclusive license by Defendant LIFEWAVE to Plaintiff to market and sell the Products.

20. Paragraph 5 of the Agreement provides for an initial term of exclusivity of 18 months, renewable upon attaining certain sales quotas as set forth in Exhibit C of the Agreement.

21. The Defendants represented in Paragraph 11 of the Agreement, that there were no pending FTC, FDA or state complaints or investigations against Defendant LIFEWAVE as a result of the product claims made by LIFEWAVE regarding the Products.

22. Paragraph 11 of the Agreement provides for the disclosure by Defendants of all data and information concerning anecdotal and formal clinical studies existing at the time the Agreement was entered into, and thereafter, concerning the Products.

23. The Defendants represented in Paragraph 11 of the Agreement that Defendant LIFEWAVE had been making product claims with

regard to "strength" and "stamina" increases associated with human usage of the Products.

24. Exhibit A of the Agreement contained further representations of claims by Defendants that human usage of the Products enhanced performance and strength, increased stamina, and relieved pain.

25. Exhibit A of the Agreement contained further representations of claims by Defendants that "the orthomolecular organic compounds contained in the Products have been determined by the FDA to be safe for use in the presence of humans." (the product claims referred to in the foregoing three paragraphs hereinafter collectively referred to the "Product Claims").

26. That notwithstanding Defendants inducements, to the Plaintiff, to market and sell the Products, and issuance of an exclusive license for that purpose, Defendants had actual and/or constructive knowledge that it was illegal to sell the Products to the public without statutory clearances from the Food and Drug Administration.

27. During all relevant times, Defendant failed or refused to conduct clinical testing as set forth in 21 Code of Federal Regulations §314.1 which require full reports of "adequate and well controlled investigations, including clinical investigations," by qualified experts to evaluate the safety of the Products.

28. During all relevant times, Defendants further failed or refused to compile "valid scientific evidence as required under 21 C.F.R. § 860.7(c)(2) including without limitation "well controlled investigations," "partially controlled studies," "objective trials without matched controls," "well documented case histories," all "conducted by qualified experts and reports of significant human experience."

29. Prior to making the Products available to the public, Defendants were required under the Act to file a "pre-market notification" with the Food Drug Administration ("FDA"). Section 360 of Act provides that:

> (k) Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe) --

30. During all relevant times, the Defendants further failed and/or refused to comply with Section 360 *et seq*, of the Act, and also 21 Code of Federal Regulations 807 to demonstrate the safety and effectiveness of the Products and the claims made in connection therewith, and further obtain "premarket approval" prior to any commercial distribution of the Products.

31. During all relevant times, Defendants had failed or refused to: submit such notification with required disclosure of trade name; intended use; classification; statement of action taken;

statement of performance standard pursuant to the Code of Federal Regulations 21 C.F.R. 807, Federal Register 8/23/77 p. 42520; submit sufficient and adequate evidence of proof of effectiveness on the basis of well controlled investigations pursuant to 21 U.S.C. §360(c)(a)(3)(B).

32. Defendants have violated the Act, subjecting themselves to the penalty and enforcement provisions of Chapter 3 of the Act, §331 *et seq.*, and §332 *et seq.*; authorizing United States District Courts with jurisdiction to restrain violations of Section 331 of the Act; and/or order the imprisonment of Defendants and/or assessment of monetary fines.

COUNT ONE

AGAINST THE DEFENDANTS
FOR FRAUD IN THE INDUCEMENT

33. That Defendant SCHMIDT individually and/or on behalf of LIFEWAVE, repeatedly represented to the Plaintiff that the Product Claims, including without limitation, strength and stamina enhancement, as well as pain relief, could be made concerning the Products as hereinbefore alleged.

34. That Defendant SCHMIDT knew or should have known that such claims could not be lawfully made without first registration and clearance from the FDA, and were therefore false when made.

35. That Defendant SCHMIDT knew or should have known that the Products could not be marketed nor sold without first clearance

from the FDA.

36. That the Plaintiff reasonably relied upon the representations of Defendant SCHMIDT.

37. That in reliance of said representations, Plaintiff entered into the Agreement with the Defendant LIFEWAVE, as hereinbefore alleged, and expended substantial funds, in excess of $750,000, in developing and implementing a marketing plan as exclusive licensee for the Product.

38. Said expenditures constitute special damages of the Plaintiff.

39. That Plaintiff's efforts marketing plan could not be implemented do to the lack of FDA compliance as hereinbefore alleged.

40. That from the date of the Agreement to immediately prior to the commencement of this action, Plaintiff repeatedly requested from Defendants the required information and documentation to substantiate that the Products were in compliance with the Act.

41. That Defendants failed or refused to disclose essential information or documentation to substantiate that the Products were compliance with the Act.

42. Defendants willful misrepresentations fraudulently induced

the Plaintiff into entering into the Agreement with Defendant LIFEWAVE.

43. Defendants willful misrepresentations fraudulently induced and proximately caused the Plaintiff into expending substantial sums of money in developing and attempting to implement a marketing plan for the Products which could not, and cannot, be legally sold to the public at large.

44. Defendants' misrepresentations were material, knowingly false when made, reasonably relieved upon by Plaintiff, proximately causing Plaintiff substantial damages.

45. Said illegal conduct on the part of the Defendants constitutes negligence *per se*.

46. Defendants conduct constitutes fraud in the inducement, rendering Defendants jointly and severally liable to the Plaintiff for actual, compensatory, restitution and special damages in the minimum amount of $1 million.

47. The said conduct of the Defendants was intentional, malicious, willful, wanton, oppressive, which actions were taken without cause or justification, and in contravention of the rights of the Plaintiff, resulting in severe damages to Plaintiff.

48. As result of the foregoing intentional, malicious, willful,

wanton and oppressive breach by the Defendants, the Plaintiff is entitled to punitive damages in the amount of $3 million.

49. As a result of the foregoing the Defendants are jointly and severally liable to the Plaintiff for the sum of $4 million.

COUNT TWO

AGAINST THE DEFENDANT LIFEWAVE
FOR BREACH OF CONTRACT

50. That the Agreement was entered into between LIFEWAVE and Plaintiff as hereinbefore alleged.

51. That the Plaintiff performed all of the obligations on his part to be performed pursuant to the contract.

52. That Defendant LIFEWAVE materially breached the Agreement by selling Products to other distributors during the minimum exclusive period.

53. That the Defendants materially breached the Agreement by failing or refusing to comply with FDA legal requirements in manufacturing and commercially distributing the Products to Plaintiff.

54. That Defendants materially breached the Agreement by illegally manufacturing and commercially distributing the Products to Plaintiff.

55. That the Defendants materially breached the Agreement by supplying Products to the Plaintiff which could not be legally sold to the public at large.

56. As a result of the foregoing, Defendants frustrated the purpose of the Agreement.

57. That by failing to accord the plaintiff all the rights and privileges contained the Agreement, the Defendants are in material breach of the Agreement.

58. That in addition to breach of the Agreement, the Defendant, LIFEWAVE has violated its legal obligation to act in good faith in the performance of a contract as set forth in Section 1-203 of the Uniform Commercial Code of the State of New York.

59. As a result of the foregoing, the Defendant LIFEWAVE is liable to the Plaintiff for actual, reliance and consequential damages in the amount of $1 million.

60. The said conduct of the Defendants was intentional, malicious, willful, wanton, oppressive, which actions were taken without cause or justification and in contravention of the contractual rights of the Plaintiff resulting in severe damages to Plaintiff.

61. As result of the foregoing intentional, malicious, willful, wanton and oppressive breach by the Defendants, directed at the

public at large, the Plaintiff is entitled to punitive damages in the amount of $3 million.

62. As a result of the foregoing the Defendants are liable to the Plaintiff for the sum of $4 million.

COUNT THREE

AGAINST THE DEFENDANTS
FOR PERMANENT INJUNCTION

63. That Defendants illegal manufacture and commercial distribution of the Products is violative of the laws of the Food and Drug Administration.

64. That the said illegal conduct on the part of the Defendants, as hereinbefore alleged, affects the safety of the public at large.

65. That unless enjoined, the public is potentially subjected to unknown and uninvestigated peril and danger.

66. Said illegal conduct on the part of the Defendants, unless enjoined, will cause irreparable damage to Plaintiff and the public at large.

67. The Plaintiff has no adequate remedy at law.

68. As a result of the foregoing, this Court should grant a permanent injunction pursuant to the powers granted it under 21 U.S.C. §332, enjoining Defendants and its agents, servants, and employees from directly or indirectly manufacturing and commercially distributing the Products, unless and until said Products are fully compliant with FDA law.

WHEREFORE, Plaintiff respectfully demands that:

a. On the FIRST COUNT, judgment be awarded in favor of the Plaintiff for Fraud in the Inducement in the minimum amount of $1 million in actual, reliance, compensatory, and/or restitution damages and $3 million in punitive or exemplary damages.

b. On the SECOND COUNT, judgment be awarded in favor of the Plaintiff for Breach of Contract in the minimum amount of $1 million in actual, reliance, compensatory, consequential and/or restitution damages and $3 million in punitive or exemplary damages.

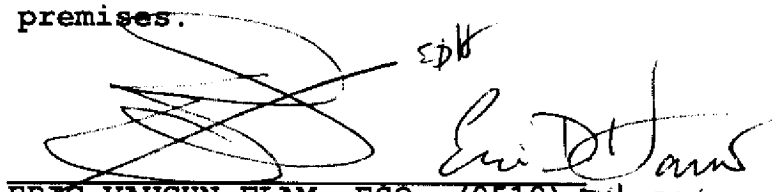
c. On the THIRD COUNT that this Court issue a Permanent Injunction, pursuant to the powers granted it under 21 U.S.C. §332, enjoining Defendants and its agents, servants, and employees from directly or indirectly manufacturing and commercially distributing the Products, unless and until said Products are fully compliant with FDA law.

d. Costs of this action be awarded plaintiff.

e. Plaintiff be awarded its reasonable attorneys' fees pursuant to contract.

f. The court grant such other and further relief as it shall deem just and proper in the premises.

Dated: New York, New York
October 14, 2004



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Plaintiff,

-against-

DAVID SCHMIDT, LIFEWAVE PRODUCTS LLC,

Defendant.

VERIFICATION

STATE OF NEW YORK)
: ss.:
COUNTY OF NEW YORK)

MARK KLINE being duly sworn, deposes and says:

I am the President of the corporate plaintiff in the above-captioned action.

I have read the foregoing Complaint and know the contents thereof; the same is true to my own knowledge, except as to the matters therein stated to be alleged upon information and belief, and as to those matters I believe them to be true.

MARK KLINE

Sworn to before me on the
5th day of October, 2004

Notary Public