SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. 5901–5940

Adulteration, Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium, and it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use and (2) adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5901. Clarimycin. Suit for injunction.

COMPLAINT FILED: On or about 2–10–58, Merritt Corp., Jersey City, N.J., filed a complaint for injunction in the United States District Court for the District of Columbia, against Marion B. Folsom, the Secretary of the Department of Health, Education, and Welfare, George P. Larrick, the Commissioner of the Food and Drug Administration, and William P. Rogers, the Attorney General of the United States.

NATURE OF CHARGE: The complaint alleged that Merritt Corp., plaintiff, was engaged in the distribution and sale of drug and cosmetic products, including *"Clarimycin,"* an antibotic lotion used in the treatment of acne pimples, which contained the active ingredient neomycin sulfate; that plaintiff had expended large sums of money on the product *"Clarimycin"*; that the defendants had, on 1–7–58 and 1–22–58, commenced libel actions against *"Clarimycin"* in the S. Dist. of Ohio, and the E. Dist. of Mich., respectively, by the seizure of plaintiff's product then being held for sale by retail customers of plaintiff; that such actions involve the same product, and the same issues, and that the defendant had interposed answers to the libel actions; that the issue in both libel actions involved a technical construction of Section 505, which, since its enactment, had not been subject to the review of the courts.

The complaint alleged further that the Government had already committed multiple seizures of plaintiff's product, and, that unless further seizures were enjoined, plaintiff would suffer irreparable harm and damage to its good will, reputation, and business; and that plaintiff would be deprived of its property without due process of law.

PRAYER FOR RELIEF: That a permanent injunction be issued restraining and enjoining defendants from instituting further proceedings, seizures, or condemnations against plaintiff's product *"Clarimycin"* under Section 304 of the Federal Food, Drug, and Cosmetic Act, pending determination of the libel

proceedings instituted by the defendants against "*Clarimycin*" in the S. Dist. of Ohio, and the E. Dist. of Mich.

DISPOSITION: The Government filed motions (1) for dismissal of the complaint on the ground that the complaint failed to state a claim on which relief could be granted, and (2) for the entry of a summary judgment, for the reason that the complaint and the affidavits of the plaintiff and the defendants showed that there was no genuine issue as to any material fact, and that defendants were entitled to judgment of dismissal as a matter of law.

On 5–5–58, the matter came on for hearing before the court, and thereafter, on 5–21–58, the court filed the following findings of fact and conclusions of law:

CURRAN, *District Judge:*

FINDINGS OF FACT

"1. On February 11, 1958, the plaintiff, Merritt Corp., filed a Complaint for Injunction seeking to restrain the defendant government officials from instituting further seizure actions against plaintiff's drug product, 'Clarimycin Anti-Biotic Acne Lotion.'

"2. Pursuant to Section 304 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 334] the defendants have caused to be instituted six seizure actions in various parts of the country against 'Clarimycin.' There was no Section 304 determination of probable cause.

"3. Each of the seizure actions instituted allege that 'Clarimycin' is a New Drug which may not be introduced into interstate commerce under the provisions of Section 505(a) [21 U.S.C. 355(a)], since an application filed pursuant to Section 505(b) [21 U.S.C. 355(b)] is not effective with respect to the drug.

"4. The active ingredient of 'Clarimycin' is the antibiotic neomycin sulfate.

"5. From 1949 to 1955 all neomycin sulfate preparations were deemed to be New Drugs requiring the filing of an application pursuant to Section 505 [21 U.S.C. 355] before the drug could be marketed in interstate commerce.

"6. In 1955 certain types of neomycin sulfate preparations were declared by the United States Food and Drug Administration no longer to be new drugs when labeled for use only for the prevention of infections in the temporary self-limiting conditions of minor cuts, burns and abrasions.

"7. Plaintiff markets its neomycin sulfate lotion preparation in interstate commerce for sale to the layman with labeling recommending use of the product for the treatment of acne.

"8. Acne vulgaris is a chronic, recurring disease condition of the skin which may last for years and which therefore requires treatment for a prolonged period of time.

"9. When viewed in the light most favorable to it, plaintiff's medical affidavits assert that topical neomycin sulfate is generally recognized by experts as safe in the treatment of acne, even when used over prolonged periods of time.

"10. Defendant's medical affidavits assert that topical neomycin sulfate is not generally recognized as safe by experts in the treatment of acne, because it has been shown to produce sensitization and cross-sensitization to streptomycin, an antibiotic valuable in the treatment of serious disease conditions. In addition, that use of neomycin sulfate for the treatment of acne is a new use for neomycin sulfate both because it has not been generally used for such a disease before and also because prolonged administration, which is required in an acne treatment, is a new method of utilizing the drug.

CONCLUSIONS OF LAW

"1. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 334, imposes no limitations upon the number of seizure actions which may be instituted under a 'New Drug' charge, i.e. that the drug is one which may not, under the provisions of Section 505 [21 U.S.C. 355] be introduced into interstate commerce.

"2. Multiple seizures based on a 'New Drug' charge may be instituted without the making of any probable cause determination under Section 304 [21 U.S.C. 334].

"3. The newness of a drug, within the meaning of the Federal Food, Drug, and Cosmetic Act may arise by reason of, among others, a new or different recommended use for the drug, or a new or different duration of administration, even though the same drug may not be a new drug when used in another disease or other duration of administration.

"4. From the affidavits submitted it appears that a difference of medical opinion exists among the experts on whether topical neomycin sulfate is generally recognized as safe for the treatment of acne.

"5. Where there is a genuine difference of medical opinion among the experts on the question of whether a drug is generally recognized as safe for the treatment of a particular disease, it must be concluded that the drug is not *generally* recognized as safe for use in the treatment of that disease.

"6. It cannot be said therefore, that the defendant government officials have acted unreasonably or arbitrarily. The medical affidavits submitted by the defendants leaves no doubt as to the good faith of the officials.

"7. The institution of lawsuits alleging violation of the Federal Food, Drug, and Cosmetic Act is a matter of discretion vested in the defendant officials.

"8. Where discretion is vested in a government official and he acts in good faith in the light of the facts he ascertains and the judgment he forms, a Court cannot restrain him from acting, on the ground that he has exceeded his jurisdiction, even if his conclusion might have been induced by an error of fact or law.

"9. The defendant officials here were properly exercising the powers of the sovereign and the Court may not enjoin that action.

"10. The Court is without jurisdiction to enjoin the defendants.

"11. Plaintiff's motion for a Temporary Injunction will be denied.

"12. There exists no genuine issue as to any material fact and defendants are entitled to judgment as a matter of law on their motion to dismiss and for summary judgment.

"13. Defendant's motion to dismiss and for summary judgment will be granted.

"Let judgment be entered accordingly."

On the same day the court ordered that the plaintiff's motion for a preliminary injunction be denied, and further ordered that defendant's motion for summary judgment to dismiss the complaint be granted.

5902. Pega Palo vine. (F.D.C. No. 40293. S. No. 72-967 M.)

QUANTITY: 405 pliofilm pkgs. at Bountiful, Utah, in possession of B & E Distributing Co.

SHIPPED: 2-21-57, from Chicago, Ill., by A-1 Import Co.

LABEL IN PART: "Pega Palo."

ACCOMPANYING LABELING: Reprints entitled "Pega Palo The Vine That Makes You Virile" and leaflets entitled "Pega Palo Fact Sheet."

RESULTS OF INVESTIGATION: Some of the reprints and all of the leaflets were printed locally for the dealer.

LIBELED: 5-31-57, Dist. Utah.

CHARGE: 502(f)(1)—when shipped and while held for sale, the labeling of the article failed to bear adequate directions for its use as an aphrodisiac and as a sex rejuvenator which were the purposes for which the drug was intended; and 505(a)—the article was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to the drug.

DISPOSITION: 10-21-57. Default—destruction.