UNITED STATES TARIFF COMMISSION

M E P R O B A M A T E

Report to the President
Preliminary Inquiry into Complaint
Under Section 337 of the Tariff Act of 1930

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UNITED STATES TARIFF COMMISSION

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C O N T E N T S

Note.--The whole of the Commission's report to the President may not be made public since it contains certain information the publication of which would result in the disclosure of the operations of individual concerns. This published report is the same as the report to the President, except that the above-mentioned information has been omitted. Such omissions are indicated by asterisks.

April 23, 1971

REPORT TO THE PRESIDENT

Introduction

On August 5, 1970, Carter-Wallace, Inc., of New York, N.Y., hereinafter referred to as complainant, filed a complaint with the U.S. Tariff Commission requesting relief under section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), alleging unfair methods of competition and unfair acts in the importation and sale of the drug meprobamate. Complainant alleged that claim 4 of U.S. Patent No. 2,724,720, owned by Carter-Wallace, Inc., specifically covers meprobamate and that the importation and sale of the drug by Zenith Laboratories, Inc., of Northvale, N.J., Davis-Edwards Pharmacal Corp., Woodside, N.Y., Rondex Laboratories, Inc., Guttenberg, N.J., Purepac Corp., Elizabeth, N.J., and Wolin's Pharmacal Corp., Melville, N.Y., hereinafter referred to as respondents, has the effect or tendency to destroy or substantially injure an efficiently and economically operated industry in the United States.

Notice of receipt of the complaint and the institution of the preliminary inquiry was published in the Federal Register (35 F.R. 3139) on August 20, 1970. Interested parties were given until October 19, 1970, to file written views pertinent to the subject matter. Upon written request of the Federal Trade Commission, the Tariff Commission extended the time for filing written views until November 18, 1970.[1/] Copies of the complaint, the notice of investigation, and the extension of time for filing written views were served upon all known interested parties.

1/ On November 18, 1970, the Federal Trade Commission submitted its views to the Tariff Commission.

The Commission conducted a preliminary inquiry, in accordance with section 203.3 of the Commission's Rules of Practice and Procedure (19 C.F.R. 203.3) to determine whether a full investigation is warranted and, if so, whether it should recommend to the President that a temporary exclusion order be issued pursuant to 19 U.S.C. 1337(f). The standard adopted by the Commission for deciding whether the issuance of such an order should be recommended (as indicated to the parties by letter notice) is whether the complainant has made a prima facie showing of violation of the provisions of section 337 of the Tariff Act of 1930, and whether, in the absence of a temporary order of exclusion, immediate and substantial injury would be sustained by the domestic industry involved.

Findings and Recommendations of the Commission

Upon conclusion of its preliminary inquiry the Tariff Commission, on March 15, 1971, unanimously ordered a full investigation. The Commission also was unanimous in its decision to recommend to the President that he issue a temporary exclusion order to forbid entry of meprobamate and products containing meprobamate in accordance with the provisions of section 337(f), until the investigation ordered is completed.

Statement of the Commission

On August 5, 1970, Carter-Wallace, Inc., of New York, N.Y. (hereinafter referred to as Carter), filed a petition with the United States Tariff Commission under section 337 of the Tariff Act of 1930 asking that the Commission recommend to the President that certain imported

pharmaceuticals be barred from entry into the United States pending the completion of the Commission's investigation to determine whether they should be permanently barred. For the reasons set out below, we agree that a temporary exclusion order should be issued.

The relevant facts are as follows. In November 1955, Carter obtained a U.S. patent on the drug meprobamate. Thereafter, Carter successfully and profitably sold this compound to more than 100 qualified pharmaceutical houses which tablet the drug and sell it.

In the period beginning October 1967, Zenith Laboratories, Inc., without obtaining a license from Carter, began importing meprobamate from overseas manufacturers into its New Jersey plant for tableting, and subsequently marketed these tablets throughout the United States. Subsequently, Davis-Edwards Pharmacal Corp. and Purepac Corp. began importing meprobamate. Carter filed infringement suits against the importers upon learning of the unlicensed sales of meprobamate in the United States. In addition to the infringement suits against respondents named in the complaint before the Tariff Commission, Carter filed suit against the United States in the Court of Claims on September 14, 1967, seeking to recover damages caused by imports of meprobamate by the U.S. Government. These infringement actions have not reached final decision.

Requirements for a temporary exclusion order recommendation

The Commission's standard for determining whether a temporary exclusion order should be recommended is (1) whether a prima facie showing of violation of section 337 has been established and (2) whether

immediate and substantial harm to the domestic industry would result if a temporary exclusion order is not issued.

Prima facie case.--In order to establish a prima facie case under section 337, it must be shown that, based upon the facts presently available to the Commission, there is reason to believe that respondents have violated the statute.

Respondents have violated section 337 if the facts show that the acts complained of--

(1) amount to an "unfair act" or an "unfair method of competition," and

(2) have the effect or tendency to (a) substantially injure an efficiently and economically operated domestic industry, or (b) prevent the establishment of a domestic industry, or (c) restrain or monopolize commerce.

The domestic industry.--The domestic industry is composed of the domestic facilities of the patentee and his licensees engaged in the manufacture of meprobamate. Carter does not manufacture bulk meprobamate but contracts with various manufacturers to provide its requirements for its own sales under Carter trade names and for resales on a royalty basis of bulk meprobamate to other drug companies. These companies sell dosage forms of meprobamate under their own trade names and manufacture combination products containing meprobamate.

The preliminary inquiry discloses that this industry is economically and efficiently operated. Carter's suppliers use modern manufacturing equipment and processing methods. The commercial success of the drug is evident from the multimillion-dollar sales level

obtained in its years on the market. Sales of meprobamate in all forms contribute very substantially to net earnings of multidivision Carter-Wallace, Inc.

Unfair acts.--There can be no doubt that the facts show the existence of a prima facie "unfair act" and an "unfair method of competition." Respondents concede that they are importing the patented substance without having obtained a license under that patent. The Commission and the courts have long held that such importations are an unfair method of competition or unfair act within the meaning of section 337. 1/ The patent has been adjudicated to be "valid, enforceable, and infringed" by the United States District Court for the Southern District of New York. 2/ The patent has never been declared invalid or unenforceable by any court.

1/ In Self-Closing Containers (Squeeze-Type Coin Purses), Investigation No. 337-18 ***, TC Publication 55, 1962, the Commission stated:

> If an article manufactured in a foreign country is made in accordance with, embodies, employs, or contains the invention disclosed in a current United States patent that has not been held invalid by a court of competent jurisdiction, it is an unfair method of competition or unfair act, within the meaning of section 337 of the Tariff Act of 1930, to import such article into the United States or sell it domestically without license from the registered owner of the patent. This determination is in accord with the applicable decisions of the United States Court of Customs and Patent Appeals. See In re Von Clemm, . . . 229 F. 2d 441, 443 (1955); In re Orion Co., . . . 71 F. 2d 458, 465 (1934); and In re Northern Pigment Co., . . . 71 F. 2d 447, 455 (1934). See also Frischer & Co., Inc. v. Bakelite Corporation, . . . 39 F. 2d 247 . . . (1930).

2/ Carter-Wallace, Inc. v. Riverton Laboratories, Inc. (304 F. Supp. 357 (S.D.N.Y. 1969)). Upheld on appeal by the Court of Appeals (U.S.C.A. 2d Cir. Docket No. 34718).

Zenith has answered the complaint before the Tariff Commission with bare allegations of patent misuse by Carter and patent invalidity owing to lack of patentable "invention." No evidence in support of these allegations was submitted or obtained during the preliminary inquiry. Similar allegations of misuse were denied by Trial Commissioner Davis on preliminary motions in the above-mentioned Court of Claims infringement suit by Carter against the United States. Misuse charges were levied against Carter by the United States in 1962, and a consent decree was entered requiring Carter to sell meprobamate on nondiscriminatory terms and at fixed maximum prices. 1/ From the absence of new data and lack of evidence of misuse subsequent to the consent decree, we are presently satisfied that Carter has offered meprobamate fairly and on a nondiscriminatory basis.

Immediate and substantial harm.--The Commission's "immediate and substantial harm" standard is more stringent than the injury standard set forth in the statute, which requires only "the . . . tendency . . . to . . . substantially injure." It follows that if the Commission's standard is met, the less stringent standard of the statute must also be met.

1/ By reason of an antitrust consent judgment entered Nov. 9, 1962, in the case of United States of America v. Carter Products, Inc., Carter was required to offer and to sell meprobamate compound, on unrestricted and nondiscriminatory terms and conditions, to every qualified pharmaceutical house placing a written order therefor. The maximum price for bulk meprobamate was set at $20 per pound with provision for adjustment in accordance with fluctuations in the Consumer Price Index.

Carter sells meprobamate at a price fixed by the consent decree. All the licensed manufacturers purchase the bulk drug from Carter and produce various meprobamate products. The offending products are made from bulk meprobamate which is produced by foreign manufacturers. The imported bulk is sold at a very small fraction of the price of Carter's resales of bulk meprobamate, causing extensive market penetration and loss of sales to Carter.

The facts obtained in the preliminary inquiry reveal that the domestic industry has undergone significant reduction in sales of meprobamate, idling of facilities for the production of meprobamate, decrease in employment, and a decline in profitability. Information obtained in the preliminary inquiry indicates that the offending imports have increased from less than 10 percent of U.S. consumption in 1966-67 to more than 20 percent in 1968-69 and more than 30 percent in 1970.

Meprobamate is already being imported in substantial quantities, and each sale made by the unlicensed importers means lost sales and lost profits for Carter. If a temporary exclusion order is not issued, respondents will be permitted to continue to expand their sales of offending imports during the remainder of the period necessary for the Tariff Commission to complete its full investigation. 1/

Carter sold bulk meprobamate at equal prices (including royalty) to more than 40 licensees in each fiscal year (ending March 31) from

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1/ The Carter patent expires in November 1972; thus, the short time remaining for the patent monopoly requires immediate exclusion of the offending imports if relief is to have any practical effect.

1964 to 1968. During this period Carter engaged as many as five domestic manufacturers to supply its bulk meprobamate requirements. In the first four months of fiscal 1971 (April-July), Carter sold meprobamate to only 13 licensees and is presently supplied by one manufacturer. These figures indicate that many licensed distributors of meprobamate have been unable to compete with low-priced imports with resultant loss of sales to Carter and the primary manufacturers.

Respondents are not precluded from making entries if the temporary exclusion order is issued. On the contrary, respondents' goods are still entitled to entry under a bond prescribed by the Secretary of the Treasury. Should respondents ultimately prevail, the temporary order is lifted and the bond is no longer necessary. However, if a permanent exclusion order issues, the Secretary may proceed against the bond covering the importations made during the pendency of the proceedings.

Conclusion

In view of the foregoing, we believe the circumstances of this case warrant that the President issue a temporary exclusion order.

Alleged Unfair Methods of Competition and Unfair Acts

Alleged violation of patent

The patent under consideration is U.S. Patent No. 2,724,720, owned by the complainant. This composition of matter patent, originally issued on November 22, 1955, to Carter Products, Inc., which was the predecessor to complainant, expires in November 1972. Complainant alleges that claim 4 of this patent specifically covers meprobamate and that said patent is being infringed by the importation into, and sale in, the United States of such meprobamate.

In Carter-Wallace, Inc. v. Riverton Laboratories, Inc. (304 F. Supp. 357 (S.D.N.Y. 1969)), the U.S. District Court for the Southern District of New York held, after a full trial on the merits, that "the patent is valid, enforceable, and infringed." The Riverton decision has since been upheld on appeal by the U.S. Court of Appeals (2d Cir. Docket No. 34718). Also, complainant is presently engaged in litigation against each of the named respondents in various jurisdictions seeking damages for infringement. No court has declared the patent to be invalid or unenforceable.

By reason of an antitrust consent judgment entered November 9, 1962, in the case of United States of America v. Carter Products, Inc. (211 F. Supp. 144), Carter was required to offer and to sell meprobamate compound, on unrestricted and nondiscriminatory terms and conditions, to every qualified pharmaceutical house placing a written order therefor. Additionally, Carter was required to make available to each such pharmaceutical house all confidential and technical

information in Carter's possession pertaining to meprobamate. This information was to enable said pharmaceutical houses to obtain an approved new drug application for meprobamate from the U.S. Food and Drug Administration. Since this consent judgment, Carter has sold meprobamate to more than 100 qualified pharmaceutical houses that tablet the drug and sell it in competition among themselves and with Carter.

It should be further noted that this consent decree fixed the maximum selling price for meprobamate, and Carter has always sold the drug either at the price authorized by the judgment or at a lower price. 1/

Complainant alleges that immediate and substantial injury is clearly shown in this case and that a temporary exclusion order under section 337(f) of the statute is the only effective remedy for the unlawful importation of this compound and the unfair methods of competition encompassed by such importation.

Respondent's answer

Respondent Zenith answers saying that it has purchased bulk meprobamate from overseas manufacturers since October 1967, imported such bulk chemical into its New Jersey firm for tableting, and marketed these tablets throughout the United States.

1/ The maximum price for bulk meprobamate was set at $20 per pound with provision for adjustment in accordance with fluctuations in the Consumer Price Index.

Respondent contends that complainant has refused to license or sell bulk meprobamate to Zenith on fair and reasonable terms and that Zenith purchases from foreign manufacturers with the knowledge and in the belief that complainant's meprobamate patent is invalid and unenforceable. Said patent has never been challenged in litigation on the ground that the patent is invalid for want of patentable "invention," i.e., because of the existence of other closely related compounds from which meprobamate is not patentably distinguishable.

Zenith also seeks to establish that said patent is unenforceable by reason of patent misuse in the maintenance of certain patent cross-license agreements on meprobamate combination products, under which the licensees are prohibited from selling bulk form meprobamate and other pharmaceutical products purchased from each licensee to others. Respondents allege that such misuse of a patent to secure a monopoly beyond the scope of the patent-protected legal monopoly amounts to an unlawful restraint of trade in violation of sections 1 and 2 of the Sherman Antitrust Act and renders the patent unenforceable.

Pending litigation

Carter has enforced its rights under the patent and has instituted five separate meprobamate infringement actions against companies that are or have been engaged in the importation or sale of infringing meprobamate, as follows:

Carter-Wallace, Inc. v. Zenith Laboratories, Inc.,
Civil Action No. 728-68 (D.N.J.);
Carter-Wallace, Inc. v. Rondex Laboratories, Inc.,
Civil Action No. 4470 (D.N.J.);
Carter-Wallace, Inc. v. Davis-Edwards Pharmacal Corp.,
Civil Action No. 70-C-369 (E.D.N.Y.);
Carter-Wallace, Inc. v. Wolin's Pharmacal Corp.,
Civil Action No. 70-C-45 (E.D.N.Y.);
Carter-Wallace, Inc. v. Barry-Martin Pharmaceuticals, Inc.,
Civil Action No. 68-516-Civ-JE (S.D.Fla.).

Each of these infringement actions, except one, is pending in various stages of pretrial discovery. The action against Barry-Martin was terminated by a consent judgment and permanent injunction prohibiting future infringement of the patent.

On September 14, 1967, complainant instituted litigation against the United States in the Court of Claims, Carter-Wallace, Inc. v. The United States (No. 322-67). Carter-Wallace charged infringement of its meprobamate patent by U.S. Government imports of meprobamate for use in its Department of Defense and Veterans Administration programs. In this litigation the Government raised, among others, defenses based on patent misuse and antitrust violations. Carter-Wallace filed motions to strike these Government defenses on the grounds that the consent judgment it entered into with the Government purged its pre-consent-judgment conduct from subsequent charges of antitrust violations on issues covered by the consent decree.

On November 6, 1971, Commissioner Davis of the Court of Claims, to whom that court referred the motions, filed an opinion with the court striking defenses raised by the Government relating to patent misuse and antitrust violations in agreements between Carter-Wallace and others entered into before the consent judgment of 1962.

Commissioner Davis found that the cross-license agreements entered into by Carter and others are within the purview of the consent judgment and are purged of charges of antitrust violations and patent misuse. Other defenses by the Government relating to marketing and pricing practices were also struck by Commissioner Davis on the grounds that Carter-Wallace had acted in accordance with the mandates of the consent judgment. The decision by Commissioner Davis is now being reviewed by the Court of Claims, pursuant to rule 55 of the Rules of the Court of Claims (28 U.S.C.). After final judgment of the rulings on these motions, the court may order a full hearing on the merits of the case.

Description and Uses

Meprobamate is the generic or nonproprietary name for 2-methyl-2-propyl-1,3-propanediol dicarbamate, a bitter-tasting white powder used as an antianxiety agent or minor tranquilizer. The antianxiety agents, of which meprobamate is the prototype and most widely used member, are a group of central nervous system depressants used to alleviate moderate degrees of anxiety and tension. They have the ability to produce mild sedation at dosage levels unlikely to cause loss of mental clarity or psychomotor control, but they are not generally effective in controlling severely disturbed psychotic patients. In case of overdosage, they have a wider margin of safety than the barbiturates, but, like the barbiturates, they may produce dependence in patients who take large doses over extended periods.

Meprobamate is included in the U.S. Pharmacopoeia, 18th revision. This drug has been used in the treatment of alcoholism, anxiety states, tension headaches, insomnia, neuroses, and premenstrual tension; it has also been claimed to be of value as a skeletal muscle relaxant and anticonvulsant. The Food and Drug Administration, however, as a result of the current review of the efficacy of drugs introduced between 1938 and 1962, has recently ordered that labeling claims for meprobamate be limited to the relief of anxiety and tension. Meprobamate is administered principally in the form of 400-milligram tablets, three or four tablets daily being the usual dosage. Serious side effects are rare. In combination with various other drugs, meprobamate is used for adjunctive therapy in the treatment of angina pectoris, depression, gastric disorders, hypertension, tension, menopausal syndrome, and obesity.

Meprobamate is sold only on prescription. Because of its potential for abuse, it is subject to Federal control under the old Drug Abuse Control Act and the newer Controlled Substances Act, which impose strict registration and record-keeping requirements on all manufacturers, distributors, and dispensers of meprobamate and other controlled drugs.

U.S. Producers

Carter-Wallace, not being a chemical manufacturer, has never produced bulk meprobamate but instead has had its requirements produced under contract by other companies having chemical manufacturing

facilities. There were five such U.S. producers in the years 1959-64, four in 1965, and three in 1966-69. During 1970, two of the remaining producers discontinued meprobamate production, leaving Millmaster-Onyx as the sole remaining U.S. producer. In 1967, and possibly in earlier years as well, one of the smaller U.S. producers imported crude meprobamate from its Canadian plant, upgraded it in its U.S. plant, and sold the purified product to Carter-Wallace. Since 1967, however, all sales have consisted of material produced in the United States by chemical synthesis.

Meprobamate was first marketed in the United States in May 1955, following approval by the Food and Drug Administration of its sale as a prescription drug. It is sold in the form of tablets and bulk powder and in combination with other drug products. Lederle Laboratories of the American Cyanamid Corp. markets meprobamate in the United States and Canada on a royalty basis with Carter-Wallace; its product is a combination of meprobamate and an anticholinergic for gastro-intestinal tract disorders. Wyeth Laboratories, a division of American Home Products Corp., purchases meprobamate powder from Carter-Wallace and markets it in the United States and most foreign countries under the trade name Equanil; it also markets combinations of meprobamate with various other drugs. In addition, more than 100 domestic pharmaceutical distributors purchase mrprobamate powder from Carter-Wallace and market generic dosage forms.

Carter-Wallace, Inc.

Carter-Wallace, Inc., was incorporated in the State of Delaware, on June 25, 1968, as a wholly owned subsidiary of Carter-Wallace, Inc., of Maryland; on November 29, 1968, it was merged with the parent company on a share-for-share basis. Its predecessor was incorporated in the State of Maryland in 1937, as Carter Products, Inc., the successor to Carter Medicine Co., a business chartered in the State of New York in 1880.

Carter-Wallace, Inc., is engaged in developing, manufacturing, and marketing in the United States prescription drugs, proprietary medicines, toiletries, cosmetics, and food specialties. The most important of the drugs, from the standpoint of net sales of the company, is meprobamate, marketed under the trademark Miltown. The company also markets nationally, on a royalty basis, a number of preparations combining meprobamate with other drugs. Among the latter are Milpath, a combination of meprobamate and tridihexethyl chloride, for treatment of gastro-intestinal tract disorders, distributed subject to a licensing arrangement with American Cyanamid; Milprem, a combination of meprobamate and conjugated estrogens for treatment of the menopause; Deprol, an antidepressant; Miltrate, a preventative medicine against attacks of angina pectoris; Appetrol, to suppress appetite and assist in dieting; Meprospan, which is meprobamate in prolonged-release capsules; and Meprotabs, which is meprobamate in unmarked coated tablets. Other leading products of the company are Carter's Little Pills, marketed since 1880; Rondomycin,

an antibiotic; 1/ Arrid deodorant; Rise shaving cream; and Nair, for removing excess hair.

Carter-Wallace, Inc., receives substantial royalties on certain of these products which are sold in the United States and foreign countries under these names or under other trade names by its licensees. Some products are exported to, or manufactured in, foreign countries by subsidiaries or agents of the company.

The company consists of four divisions. Wallace Pharmaceutical Division compounds and packages prescription drugs. Carter Products Division is responsible for the output of advertised drugs and toiletries. Wallace Laboratories Division is engaged in the development of new prescription drugs through research. The Frenchette Division manufactures a variety of food products.

During recent years, prescription drugs and bulk pharmaceuticals, combined, have accounted for a little more than 50 percent of the value of net sales of Carter-Wallace, Inc. Foreign sales in recent years have accounted for about 15 percent of the company's net sales.

The executive offices of Carter-Wallace, Inc., are located in New York City. The company owns a plant and laboratory on a 500-acre site in Cranbury, N.J. Other plants are situated in Nomence, Ill.; Los Angeles; Montreal, Canada; Mexico City; Folkestone, England; and Paris. Another laboratory is in Montreal. Overseas subsidiaries

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1/ The company was granted exclusive U.S. marketing rights for Rondomycin in January 1969, under an agreement with Charles Pfizer & Co., Inc.

and affiliates have plants in France, the United Kingdom, Luxembourg, Mexico, Australia, Hong Kong, India, Pakistan, and South Africa.

Financial data: Sales, net earnings, expenses, and profits--The annual report of Carter-Wallace, Inc., for the fiscal year ended March 31, 1970 showed that the company had consolidated net sales of $125.1 million, compared with $113.2 million for the fiscal year ended March 31, 1969. Net earnings 1/ in fiscal 1970 were nearly $18.3 million, compared with less than $9.6 million in fiscal 1969. Capital expenditures were $3.1 million in fiscal 1970, whereas they had been $4.2 million in fiscal 1969. The cost to the company for research on new products (mostly ethical drugs) was almost $7.3 million in the fiscal year ended March 31, 1970, compared with more than $6.3 million in the preceding fiscal year. Royalty income amounted to $1.9 million in fiscal 1969 and to $1.7 million in fiscal 1970. Inventories were at a high level at the close of fiscal 1970, being valued at nearly $15.8 million then in comparison with about $12.5 million on March 31, 1969.

During the period 1966-70, sales of meprobamate in all forms by Carter-Wallace, Inc. declined slightly each year, while at the same time, in contrast, the consolidated net sales of all of the company's divisions and subsidiaries rose by 50 percent. Thus, the ratio of sales of meprobamate to total sales declined substantially. Nevertheless, in the fiscal year 1970, meprobamate sales still accounted for the major portion of the company's income on sales of all prescription

1/ Annual earnings per share of common stock were $2.42 for fiscal 1970, compared with $1.27 for fiscal 1969.

drugs and bulk pharmaceuticals which in that year accounted for less than half of the consolidated net sales of the company.

U.S. primary producers

As indicated previously, Carter-Wallace, Inc., does not manufacture the meprobamate powder. This basic manufacturing, as well as some processing, is done for the company by primary producers in accordance with the company's patent and with complete reliance on Carter-Wallace for research and development. The chief primary producers of meprobamate powder for Carter-Wallace are three large U.S. chemical manufacturers--Millmaster-Onyx Corp., Abbott Laboratories, Inc., and the Penick Division of CPC International, Inc. These firms are authorized to use the Carter-Wallace patent in manufacturing the bulk meprobamate for the company. Between 1959 and 1970, these three firms, especially Millmaster-Onyx, provided the company with most of its meprobamate powder. Purchases from foreign suppliers were very small.

Millmaster-Onyx Corporation, the largest individual supplier of bulk meprobamate to Carter-Wallace, Inc., and currently the sole supplier, has manufactured the product under contract exclusively for Carter-Wallace since 1955. All this meprobamate has been produced by the Berkeley Chemical Department of Millmaster Chemical Company, a division of Millmaster-Onyx, in a plant located in Berkeley Heights, N.J.

Sales of meprobamate by Carter-Wallace were considerably reduced by 1970. Consequently, purchases of this product by Carter-Wallace

from Millmaster-Onyx were severely reduced. Millmaster officials maintained--

> the progressive diminution of demand for meprobamate has resulted in serious and sizable reduction in our efficiency and our profits and that we have been and will continue to be substantially and irreparably injured by the importation of this product.

Some of the workers at Millmaster-Onyx involved in meprobamate production were discharged, as a result of the diminution of purchases by Carter-Wallace. Other workers in production, maintenance, warehousing, and laboratory activities would be affected by further diminution or termination of production. * * * * *

Production and Sales of Bulk Meprobamate

Production and sales by the primary producers

Available data on U.S. production and sales of medicinal grade meprobamate (including that produced by purification of imported crude) are given below. These statistics are taken from the Commission's annual report Synthetic Organic Chemicals, United States Production and Sales and are based on data reported annually by the licensed producers. Since all sales were made to Carter-Wallace in bulk, data for production (allowing for inventory changes and processing losses) are very nearly equal to those shown for sales.

It is noteworthy that sales in 1965 and 1966 reached a level of 1.2 to 1.3 million pounds annually; but beginning in 1967--the year when imports of bulk meprobamate first entered the U.S. market--sales dropped to a level of 900,000 pounds annually. * * * * *

Bulk meprobamate: U.S. production and sales by the primary producers, 1959-69

Year	Production	Sales		
		Quantity	Value	Unit value
	1,000 pounds	1,000 pounds	1,000 dollars	Per pound
1959	1,192	1,138	4,129	$3.63
1960	989	970	3,480	3.59
1961	1,159	1,011	3,089	3.06
1962 1/	1,168	1,117	3,243	2.90
1963 1/	1,063	957	2,912	3.04
1964	1,173	902	2,430	2.69
1965	1,179	1,272	3,344	2.63
1966	1,206	1,244	3,163	2.54
1967	1,260	913	2,329	2.55
1968	733	922	2,362	2.56
1969	868	2/	2/	2/

1/ Data include small quantities of mebutamate.
2/ Data withheld to avoid disclosure.

In addition to the licensed producers of bulk meprobamate, one infringing producer, Riverton Laboratories, Inc., began production of bulk meprobamate in July 1963, and admittedly produced some 40,000 pounds until it was enjoined from further infringement in December 1969 by the U.S. District Court. Approximately 90 percent of Riverton's production was sold as meprobamate tablets to the U.S. Government.

Purchases by Carter-Wallace

Carter-Wallace furnished confidential data concerning its purchases of bulk meprobamate from domestic and foreign manufacturers for the years 1959-70. Total annual purchases fluctuated somewhat during the years 1959-64 but showed no clearly defined trend; purchases in 1965 and 1966 increased somewhat above the 1959-64 average, but then declined in 1967-69 to a level somewhat below that average. In 1970,

purchases declined still further. * * * * *

Imports of bulk meprobamate by Carter-Wallace came principally from the United Kingdom and amounted to a small part of the total quantity purchased during the years 1959-70. * * * * *

Sales of bulk meprobamate by Carter-Wallace

* * * * * Carter-Wallace sold bulk meprobamate in the fiscal years ending March 13, 1959-63 to only a few customers; most of the quantity sold in each of these years was purchased by Wyeth Laboratories Division of American Home Products Corp., which sells meprobamate under the trade name Equanil. In addition to the purchase price, Carter-Wallace received royalty payments from the purchasers equivalent to 5 percent of the value of their sales of meprobamate tablets.

Under the terms of the consent decree of November 9, 1962, Carter-Wallace was required to sell bulk meprobamate on equal terms to all qualified pharmaceutical companies seeking to buy, with a few exceptions for contracts already in effect concerning sales of meprobamate for use in combination products. All sales since fiscal 1963 were made at prices specifically allowed under the terms of the consent decree, 1/ and most sales were made at prices which included an amount in lieu of royalty payment. * * * * * *

As a result of the consent decree, beginning with fiscal 1964, there was a large number of purchasers (not under 40 in each of the years 1964-68). The total quantity of bulk sales in the years 1964-67 averaged substantially more than in 1959-63, and Wyeth's share of

1/ See footnote 1 on page 6.

the total dropped considerably. Sales have declined since 1967; during the first four months of fiscal 1971, sales were at an annual rate substantially less than the 1959-63 average. Concurrently, the number of purchasers has severely declined and Wyeth's share of the total has increased considerably. * * * * *

Sales of Meprobamate in Dosage Forms

Sales by Carter-Wallace

Carter-Wallace's sales of meprobamate in dosage forms (Miltown, Meprotabs, and Meprospan) declined substantially in both quantity and value from fiscal 1966 through the first four months of fiscal 1971. Sales of meprobamate combinations in dosage forms (Milpath, Milprem, Miltrate, Appetrol, Appetrol SR, and Deprol) also declined, but to a lesser extent, during the same period. * * * * *

Pharmacy purchases of branded and generic meprobamate tablets

A survey on pharmacy purchases of pharmaceutical products conducted by a private market research organization developed the following data on branded and generic meprobamate in 400-milligram tablets and capsules, which are by far the most important dosage forms of this drug. During the period under consideration (April 1967 to September 1970), the total number of tablets purchased remained at a fairly constant level. * * * * * The branded products declined somewhat, while the generic products increased correspondingly. However, the share of those generic products made from bulk meprobamate purchased from Carter-Wallace has been drastically reduced, while the share of

those generic products made from allegedly infringing meprobamate has increased from 1 percent to one-third of the total. Approximately 90 percent of meprobamate sales are made through drug stores, the remainder being sold to hospitals and government agencies. * * * * *

Comparable data on hospital and government purchases of meprobamate tablets are not available. It may reasonably be presumed, however, that generic products account for a larger share of this market than of the drugstore market, because there is more price competition, often with competitive bidding, in the field of institutional and governmental sales. Moreover, the retail pharmacist must stock enough of the leading brand-name products to meet the demand; he can purchase generic meprobamate only to the extent that physicians write generic prescriptions. A nation-wide audit of pharmacy prescription records shows that about 32 percent of new prescriptions for 400-milligram tablets and capsules called for generic meprobamate in the fiscal year ending March 31, 1968; this percentage has now increased to about 40 percent of the total in fiscal 1970 and the first six months of fiscal 1971. Thus it appears that, to an increasing extent, physicians are prescribing generic meprobamate rather than the branded product.

U.S. Government purchases of meprobamate tablets

Data, which may be incomplete, on U.S. Government purchases of meprobamate tablets are shown below for the years 1966-69. (Small amounts of 200-milligram tablets were converted to the equivalent number of 400-milligram tablets.) According to these data, Government

purchases of tablets made from bulk meprobamate supplied by Carter-Wallace amounted to less than 12 percent of the total quantity during the period 1966-69. The remainder was obtained either from infringing production by Riverton Laboratories or from allegedly infringing imports.

Meprobamate tablets: U.S. Government purchases, by sources, 1966-69

Source	Quantity	Value	Unit value
	1,000 tablets		Per 1,000 tablets
Denmark	213,108	$708,671	$3.33
Licensed domestic sources	30,803	588,320	19.10
Infringing domestic source	21,774	119,293	5.48
Other domestic source 1/	17	1,827	105.00
Total	265,702	1,418,111	5.34

1/ This source has purchased bulk meprobamate from Carter-Wallace and has also made allegedly infringing imports. It is not possible to determine whether the tablets sold to the Government were made from domestic or imported bulk. No explanation for the high unit value of this transaction is available.

Allegedly Infringing Imports of Bulk Meprobamate

* * * * * Importation of bulk meprobamate began in October 1967. Three pharmaceutical companies--Davis-Edwards, Purepac, and Zenith--account for most of the imports of bulk meprobamate. * * * * * Five smaller importers have made one or two entries each.

Three foreign manufacturers have supplied all the known meprobamate imports: A/S Syntetic in Denmark, Wasserman in Italy, and Micro Chemicals, Ltd., in Canada. All informants agree that Wasserman does little or no chemical manufacturing but imports all or most

of its meprobamate, possibly as the crude, from Denmark or other sources. A/S Syntetic appears to be a major producer of meprobamate and is able to undersell the other producers by a considerable margin. Carter-Wallace officials believe that Syntetic's exports of meprobamate are subsidized by the Danish Government. Whether this is true or not, all or most of the imports are now coming from Denmark.

Partial data on imports of bulk meprobamate, except those by Carter-Wallace or by the one U.S. producer that imported crude meprobamate in 1967, were obtained by invoice analysis. * * * * * For various reasons, including the difficulty of locating all the pertinent entry papers and the failure of some entry documents to give the exact identity of the imported material, 1/ it was not possible to obtain complete data on imports of meprobamate. The quantity entered by two of the importers, as verified by invoice analysis, was about 30 percent less than the actual imports reported by the two companies for the period under consideration. * * * * * The following table shows estimated imports of allegedly infringing bulk meprobamate for the period October 1967 to July 1970 (prepared by assuming that the verified imports understate the actual imports by 30 percent) plus the meprobamate content of known purchases of imported meprobamate tablets by the U.S. Government. * * * * *

1/ Some entry papers give only the statutory description, e.g., "drugs, n.e.s.," which is not sufficient to identify a product, such as meprobamate, which is classified in a "basket" provision of the Tariff Schedules.

Meprobamate: Estimates of allegedly infringing U.S. imports, 1966-1969 and January-July 1970

Year	Quantity
	1,000 pounds
1966	84
1967	83
1968	373
1969	294
1970 (Jan.-July)	246

U.S. Consumption of Meprobamate

Since exports of meprobamate are negligible, U.S. consumption, for practical purposes, equals Carter-Wallace's domestic and foreign purchases plus infringing U.S. production plus the allegedly infringing imports. According to the best available data, U.S. consumption of meprobamate has remained fairly constant from 1966 through July 1970. The ratio of the allegedly infringing imports to consumption was less than 10 percent in 1967, more than 20 percent in 1968 and 1969, and more than 30 percent in the period January-July 1970. * * * * *

Prices

* * * * *

The bottle containing 1,000 400-milligram tablets accounts for the largest volume of meprobamate in dosage form sold to the trade. On the basis of information gathered by the staff of the Commission from a variety of sources, 1/ the prices charged to retailers for this

1/ From catalogs and sales literature of pharmaceutical firms concerned, and from Drug Topics Red Book for 1971.

item by leading domestic pharmaceutical distributors of generic meprobamate vary considerably; in 1970 such wholesale prices ranged from a low of $8.00 (Richlyn) to a high of $49.00 (Interstate Drug). Prices charged to retail druggists by some of the leading domestic distributors for the principal dosage forms of generic meprobamate are shown below.

Wholesale prices charged by certain leading U.S. distributors for principal dosage forms of generic meprobamate in 1970

Distributor	400-mg. tablets		200-mg. tablets
	Per 100	Per 1,000	Per 100
McKesson	$4.95	$41.95	$3.25
Purepac	3.98	34.96	2.35
Spencer-Mead	1.65	14.50	1.45
Carroll	1.50	9.95	1.45

The wide disparity in wholesale prices is attributable primarily to the source of bulk meprobamate to which individual distributors have access. For example, McKesson Laboratories purchases its meprobamate powder from Carter-Wallace, while the low-priced companies presumably obtain allegedly infringing imported powder.

Prices to the trade for generic meprobamate slumped sharply during the early months of 1969. These prices staged a recovery later in the same year and in 1970, rising to at least the levels of 1968.