

Complaint

87 F.T.C.

IN THE MATTER OF  
WARNER-LAMBERT COMPANY

OPINION, ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SEC.  
7 OF THE CLAYTON ACT

*Docket 8850. Complaint, June 30, 1971—Order, April 27, 1976*

Opinion, Findings of Facts and Conclusions of Law that the acquisition by Warner-Lambert of Morris Plains, N.J., a major American industrial corporation and a leader in the drug business, of Parke, Davis & Company, has or may substantially lessen competition in the following five therapeutic submarkets of the overall drug manufacturing market: (1) thyroid preparations, (2) cough remedies, (3) cough drops and lozenges, (4) normal serum albumin, and (5) tetanus immune globulin. The order vacates the initial decision of the administrative law judge; adopts the Commission's own Findings of Facts and Conclusions of Law; and directs each party within 30 days to file with the Commission a proposed form of order appropriate to the decision, together with a supporting memorandum.

*Appearances*

For the Commission: *Paul R. Teetor, Thomas P. Athridge, Robert D. Jacobs and Sidney A. Shapiro.*

For the respondent: *Herbert A. Bergson, Howard Adler, Jr., Mary-Margaret Gillen and Michael D. Ridberg, Bergson, Borkland, Margolies & Adler, Washington, D.C. Mudge, Rose, Guthrie & Alexander, New York City.*

COMPLAINT

The Federal Trade Commission has reason to believe that Warner-Lambert Company (hereafter "Warner-Lambert"), a corporation and the respondent herein, has acquired Parke, Davis & Company (hereafter "Parke, Davis"), a corporation, in violation of Section 7 of the Clayton Act, as amended (15 U.S.C. §18); therefore, pursuant to Section 11 of the Clayton Act, as amended (15 U.S.C. §21), it issues this complaint, stating its charges in that respect as follows:

1. DEFINITIONS

For purposes of the complaint the following definitions shall apply:

- (a) "Drugs" are medicines, both pharmaceutical and biological, in dosage form and are here restricted to those intended for human use.
- (b) "Ethical" drugs are those for which a prescription is required or which, although sold over the counter without a prescription, are primarily promoted to the medical profession.

(c) "Proprietary" drugs are those which are promoted primarily to the consuming public.

(d) Any reference herein to Warner-Lambert or to Parke, Davis shall be deemed to include all subsidiary corporations unless the context requires otherwise.

## 2. ACQUISITION

On November 13, 1970, pursuant to an Agreement and Plan of Merger dated August 25, 1970, Warner-Lambert, a Delaware corporation with its principal office at Morris Plains, New Jersey, through a wholly-owned subsidiary, Tabor Company, a Michigan corporation, acquired ownership of all or substantially all the stock of Parke, Davis, a Michigan corporation with its principal place of business at Detroit, Michigan. At the time of the acquisition both Warner-Lambert and Parke, Davis were engaged in interstate commerce within the meaning of Section 7 of the Clayton Act, as amended.

## 3. ACQUIRING COMPANY

At the time that it acquired Parke, Davis, Warner-Lambert was a major American industrial corporation and a leader in the drug business. In 1969 Warner-Lambert's total sales were \$808 million and total assets \$572 million, ranking it approximately 138th largest in sales and 165th largest in assets among American industrial corporations. Warner-Lambert has foreign operations, with some 70 owned or leased plants in 47 countries.

Warner-Lambert began business as William R. Warner & Co., later Warner-Hudnut, Inc., the product of a 1916 merger between a cosmetics company and a chemical company. Its total sales in 1954 were \$48 million. Thereafter, it embarked upon an extensive acquisition program, the most important being the acquisition of the Lambert Co. (Listerine mouthwash) in 1955. There followed acquisitions of the makers of such well-known proprietary drugs as Bromo-Seltzer (effervescent analgesic), Smith Brothers (cough drops), Sloan's (liniment) and others.

Warner-Lambert makes extensive use of advertising and other promotional programs in marketing its products. Its domestic advertising and promotion budget now approximates \$80 million yearly. Its products are advertised on nearly half of all TV network shows. In 1969, Warner-Lambert's consumer products divisions ranked fourth among all proprietary drug manufacturers in the country, with proprietary drug sales to U.S. drugstores and hospitals of \$57 million, representing 6.4 percent of total U.S. sales of about \$900 million.

By 1953 Warner-Lambert (then Warner-Hudnut) had also entered the manufacture of ethically promoted drugs through the acquisition of Chilcott Laboratories (formerly the Maltine Company). This business was gradually expanded by Warner-Lambert. Today about 300 "detail" men service the medical profession. During the decade of the 1960's Warner-Lambert's growth as an ethical pharmaceutical manufacturer was partly internal and partly by acquisitions, *e.g.*, in the dermatological field — Texas Pharmacal Co., in the biologicals field — Elizabeth Biochemical Laboratory, in the medical equipment and instrumentation field — American Optical Co., and in foreign drug manufacturing, notably the acquisition of the European firm, Vismara Terapeutici Sp. A.

In product research and development, Warner-Lambert employs approximately 500 persons and spends about \$30 million yearly. Its primary research and development efforts are on ethical pharmaceuticals and optics, including medical equipment and instrumentation.

Warner-Lambert has been and is now a rapidly growing firm. By 1969 (through its Warner-Chilcott division) it had become the 15th largest manufacturer of ethical drugs in the Nation, with sales to drugstores and hospitals of \$87 million, or 2.3 percent of the \$3.8 billion U.S. total for that year. In the overall hospitals-drugstores drug market, both ethical and proprietary, it ranked 12th among U.S. companies, with about 3.1 percent of \$4.7 billion total U.S. sales.

#### 4. ACQUIRED COMPANY

Prior to acquisition by Warner-Lambert, Parke, Davis was one of the nation's leading old-line pharmaceutical houses. Founded in 1866, it achieved its present market position largely by internal growth. In 1969 Parke, Davis' total sales were \$274 million and its total assets \$399 million. It was the 340th largest in sales and 218th largest in assets of all American industrial corporations. It also had extensive foreign operations in 43 countries, including manufacturing plants in 22 of them.

Over the years Parke, Davis built up one of the most extensive product lines in the business. Its pharmaceutical and biological manufacturing facilities are among the most diverse in the Nation. Its catalogue lists some thousand products. It is largely independent of the drug wholesalers on whom most manufacturers must depend by virtue of its unusual nationwide network of 23 warehouses and its sales force of about 1,000 "detail men" who promote its products directly to physicians and hospitals, one of the largest such detail forces in the industry. Its research and development laboratories are among the oldest, largest and best qualified in the industry, employing 700-800

persons. It spends nearly \$20 million yearly on product research and development. In 1969 Parke, Davis' domestic sales of \$110 million of ethically promoted drugs made it the 11th ranking domestic seller, with 2.9 percent of the \$3.8 billion hospitals-drugstores market for ethical drugs.

In 1969, Parke, Davis commenced the organization of a new Consumer Products Division. That Division had initial sales of about \$27 million. In 1970 Parke, Davis' articles of incorporation were amended to permit expansion of its activities throughout a broad "health" field, and it undertook a more aggressive promotional policy to expand its product line and to improve its existing market position, particularly in the hospitals-drugstores proprietary drug market where it ranked 44th among all sellers.

Among sellers of drugs of all kinds, both ethical and proprietary, to hospitals and drugstores, Parke, Davis ranked 14th, with 2.4 percent of \$4.7 billion sales in 1969.

#### 5. TRADE AND COMMERCE

The drug industry is a large and expanding one. The value of shipments by U.S. pharmaceuticals manufacturers rose steadily from about \$900 million in 1947 to \$4.7 billion in 1967 and the value of shipments by U.S. biologicals manufacturers during the same period rose from about \$40 million to about \$173 million. Pharmaceuticals shipments in 1967 totaled \$4.1 billion and were divided between ethical and proprietary drugs in a ratio of \$3.0 billion to \$1.1 billion. Long-run, the trend in the drug manufacturing industry has been toward gradual reduction in the number of firms engaged therein. The number of U.S. companies producing drugs decreased from 1,123 in 1947 to 791 in 1967.

In particular drug industry submarkets, such as those specified later in Paragraph 6, the top four or at least the top eight sellers in each such submarket commonly control 75 percent or more of the business. Moreover, the top 20 among all sellers of pharmaceutical drugs (SIC 2834) between 1947 and 1967 increased their aggregate market share from 64 percent to 73 percent. Within the top 20 pharmaceutical firms, the market position of the top eight after declining somewhat during the late 1950's has since held its ground and shows some tendency now to rise. It was at about the 40 percent level in 1967.

Research for and development of new or improved drugs is an important element for success in the drug industry. Generally such research, testing and related facilities are expensive and time-consuming. Such research, testing and related facilities, together with the control of patents; possession of heavily promoted and successful trade names, and of nationwide distribution facilities, including large and

established "detail" forces for ethical promotions and the ability to engage in expensive advertising programs for the promotion of proprietary drugs, tend to raise substantial barriers to entry into the drug industry, to limit competition within the industry and in submarkets thereof, and to make the existing drug firms, and particularly the larger drug firms, the most likely sources of new competition with regard to particular drug product submarkets in which they do not presently compete.

Parke, Davis and Warner-Lambert have each made substantial commitments to research and development, have operated substantial research and development programs in the past, and each stands among the leading U.S. firms in capacity and capability to conduct research and development. In addition, each was, prior to the merger complained of herein, possessed of patent rights, heavily promoted trade names, nationwide distribution facilities, large and established "detail" forces, substantial advertising budgets, and other competitive advantages which made each one of these firms among the most likely to enter or improve its competitive position in drug submarkets where it was not already a significant competitive factor.

#### 6. MARKETS ADVERSELY AFFECTED

The acquisition of Parke, Davis by Warner-Lambert tends substantially to lessen actual and potential competition in drug manufacturing generally, in the ethical segment thereof and in, among others, the following relevant product submarkets, all of which are nationwide in geographic scope and all of which are highly concentrated.

In some such submarkets substantial existing ("SE") competition between the parties and with others has been eliminated.

In other such submarkets where one party ranked among the top four or eight sellers, with a significant or at least not insignificant market share, the acquisition has ended all likelihood that existing, imminent or recent ("E/I/R") competition by the other, with that other firm's many competitive advantages, would have grown to more substantial proportions.

In other such submarkets where one party ranked among the top four or eight sellers, with a significant or at least not insignificant market share, the acquisition has eliminated the other party as a potential entrant ("PE") into competition. With respect to such submarkets, special circumstances such as marketing of the same product in a different geographic market or of an only slightly different product in the same market combined with the many competitive advantages of the other party served to make such other party one of the most likely entrants into competition.

Aggregate sales in these 55 submarkets in 1969 totaled about \$1,800 million.

#### A. *Hormones*

Drugs affecting the endocrine glandular system and related compounds constitute an important part of the pharmaceuticals industry. Sold ethically, domestic shipments thereof in 1969 were valued at \$497 million. The following constitute well-defined and significant hormone submarkets:

- (1) Thyroid Preparations (SE)
- (2) Anti-thyroid Preparations (PE)
- (3) Oral Contraceptives (E/I/R)
- (4) Progestogens, Except Oral Contraceptives (PE)
- (5) Anabolic Agents (E/I/R)
- (6) Adrenocortical Extract (PE)
- (7) ACTH (PE)
- (8) Chorionic Gonadotropins (PE)
- (9) Topical Corticoid with Anti-infective Combinations (E/I/R)

#### B. *Neuropharmacals*

Pharmaceutical preparations acting on man's central nervous system and sense-organs constitute the largest single segment of the pharmaceutical market. Shipments of such drugs by U.S. manufacturers in 1969 approximated \$1,373 million. Just over 70 percent were promoted ethically. The following constitute well-defined and significant neuropharmacal submarkets:

- (1) Effervescent Analgesics (PE)
- (2) Anorexiant (Non-amphetamine) (E/I/R)
- (3) Anti-Parkinsonism Drugs (E/I/R)

#### C. *Cardiovascular Drugs*

Preparations acting on the human cardiovascular system are an important segment of the pharmaceutical market. In 1969 shipments of cardiovascular drugs by U.S. manufacturers approximated \$267 million. Virtually all were promoted ethically. The following constitute well-defined and significant cardiovascular submarkets:

- (1) Anti-Anginal Drugs (E/I/R)
- (2) Anti-arrhythmics (PE)

#### D. *Respiratory Drugs*

Among the oldest kinds of pharmaceutical preparations are those drugs acting on the respiratory system. Manufacturers' shipments of

such drugs for human use in the United States were valued at \$490 million in 1969, of which about \$259 million were promoted ethically and \$222 were proprietaries. The following constitute well-defined and significant respiratory drug submarkets:

- (1) Cough Remedies (SE)
- (2) Cough Drops and Lozenges (SE)
- (3) Antitussives and Expectorants (E/I/R)
- (4) Cold Remedies (E/I/R)
- (5) Oral Decongestants (E/I/R)
- (6) Oral Decongestants (Ethical, OTC) (F/I/R)
- (7) Topical Decongestants (E/I/R)
- (8) Anti-histamines (PE)
- (9) Bronchial Dilators (E/I/R)

#### E. *Gastro-Intestinal Drugs*

Pharmaceutical preparations acting on the human digestive system make up another important part of the pharmaceutical industry. In 1969 shipments of all U.S. manufacturers of this kind approximated \$430 million. The following constitute well-defined and significant gastro-intestinal drug submarkets:

- (1) Antacids (E/I/R)
- (2) Gastric Secretory Inhibitors (E/I/R)
- (3) Irritant Laxatives (SE)
- (4) Irritant Laxatives (Ethical) (SE)
- (5) Digestive Enzymes (PE)
- (6) Lipotropics (PE)

#### F. *Skin Preparations*

Pharmaceutical preparations acting on the skin constitute a significant part of the drug market. Total shipments by manufacturers of such products in 1969 were valued at \$274 million, of which about 40 percent were ethical and 60 percent were for proprietary marketing. The following constitute well-defined and significant skin preparations submarkets:

- (1) Topical Proteolytic Enzymes (PE)
- (2) Anti-Hemorrhoidal Preparations (E/I/R)
- (3) Liniments (E/I/R)
- (4) Emollient/Protective Dermatological Preparations Promoted Ethically (PE)
- (5) Sunscreen Products (PE)
- (6) Hypo-allergenic Cosmetics (PE)

### G. *Vitamins*

Vitamin compounds constitute an important segment of the drug market. Total shipments by U.S. manufacturers of vitamins in 1969 amounted to \$253 million, of which about \$246 million were domestic shipments. Ethical sales exceeded proprietary sales about six to four. The following constitute well-defined and significant vitamin submarkets:

- (1) Prenatal Vitamins (E/I/R)
- (2) Therapeutic Vitamins (With Minerals) (E/I/R)
- (3) All Vitamins (Ethical) (E/I/R)

### H. *Anti-Infectives*

Pharmaceutical preparations affecting parasitic and infective diseases constitute a large and rapidly growing segment of the drug manufacturing industry. Total shipments by manufacturers of anti-infective agents, except corticoid-anti-infective combinations, in 1969 amounted to about \$876 million, of which about \$816 million were domestic shipments. The ethical-proprietary sales ratio was nearly four to one. The following constitute well-defined and significant anti-infective submarkets:

- (1) Antibiotics For Gram Negative Bacterial Infections (SE)
- (2) Ampicillin (PE)
- (3) Anti-pseudomonas Drugs (PE)
- (4) Urinary Antibacterials (Non-Sulfa) (E/I/R)
- (5) Mouthwash (E/I/R)
- (6) Breath Fresheners (PE)

### I. *Biologicals*

Biological products prepared for therapeutic or diagnostic medical purposes include blood and blood derivatives, vaccines and antigens, antitoxins, toxoids and toxins for immunization, therapeutic immune serums and diagnostic products, including allergenic extracts, poison ivy and poison oak extract. Total shipments by U.S. manufacturers in 1967 approximated \$167 million. These are all ethical products. The following constitute well-defined and significant biologicals submarkets:

- (1) Normal Human Serum Albumin (PE)
- (2) Immune Serum Globulin (PE)
- (3) Tetanus Immune Globulin (PE)
- (4) Diagnostic Products (Blood Chemistry) (PE)
- (5) Diagnostic Products (Blood Coagulation) (PE)
- (6) Pregnancy Tests (E/I/R)



### J. *Medical Electronic Equipment*

The recent application of electronics to the practice of medicine has resulted in development of much new equipment for hospitals and physician's offices, much of it in the fields of cardiac disease diagnosis and patient monitoring. The value of all manufacturers' shipments of electronic medical equipment is now probably of a magnitude of \$300 million or more yearly. The following constitute well defined and significant submarkets for medical electronic equipment.

- (1) Electrocardiographs (E/I/R)
- (2) Patient Monitoring Equipment (PE)

### K. *Fine/Bulk Chemicals*

Fine or bulk chemicals are those suitable for use as pharmaceuticals, either mediately or immediately. Among the well-defined and significant fine/bulk chemicals sub-markets are those for:

- (1) Pyridine (PE)
- (2) Picoline (PE)
- (3) Niacinamide (PE)

## 7. COMPETITIVE EFFECTS OF THE ACQUISITION

Warner-Lambert's acquisition of Parke, Davis has at one stroke raised the former's rank among all American drug manufacturers serving the hospitals/drugstores market from 12th to 3rd place and from 15th to 5th place in the ethical sector thereof. It has increased its share of the \$4.7 billion U.S. hospitals-drugstores market from 3.1 percent to 5.5 percent and its share of the \$3.8 billion ethical segment thereof from 2.3 percent to 5.2 percent. Concentration of sales in the hands of the eight largest sellers in the hospitals-drugstores drug market has been increased as a result of this merger from about 40.0 percent to about 41.7 percent, and in the ethical segment thereof concentration has been increased from about 44.1 percent to about 45.1 percent.

As a result of said acquisition competition may be substantially lessened in the nationwide drug manufacturing market, in its ethical and proprietary segments, and in various submarkets thereof, all nationwide in geographic scope, including, among others, each of the submarkets set out in Paragraph 6 hereof, by increasing concentration as alleged above and also in the following ways, among others:

- (a) Actual and potential competition between Parke, Davis and Warner-Lambert has been eliminated and actual and potential competition with others has been eliminated or substantially lessened;
- (b) Parke, Davis, which has long been one of the most significant

firms in the drug industry, in terms of research, distributional and promotional resources and broad resource flexibility has now been completely and permanently eliminated as an actual or potential independent competitor in countless product lines throughout the drug industry;

(c) Entry or growth of new competition may be further inhibited;

(d) The acquisition is likely to encourage a tendency to additional acquisitions or mergers, and to thereby further increase concentration.

#### VIOLATION

By reason of all the foregoing, the acquisition of Parke, Davis' stock by Warner-Lambert constitutes a violation of Section 7 of the Clayton Act, as amended (15 U.S.C. §18).

INITIAL DECISION BY ANDREW C. GOODHOPE, ADMINISTRATIVE  
LAW JUDGE

AUGUST 2, 1974

#### STATEMENT OF PROCEEDINGS

[1] On June 30, 1971, the Commission issued its complaint against respondent charging it with violation of Section 7 of the Clayton Act, as amended (15 U.S.C. §18). A copy of the complaint and notice of hearing were served upon respondent, and respondent thereafter appeared by its counsel and filed an answer admitting certain of the allegations of the complaint but denying that it had violated Section 7 of the Clayton Act.

[2] Extensive hearings were thereafter held, at which time testimony and documentary evidence were offered in support of and in opposition to the allegations of the complaint. At the close of all the evidence and pursuant to leave granted by the administrative law judge, proposed findings of fact, conclusions of law, briefs and proposed orders were filed by counsel supporting the complaint and counsel for the respondent.

Proposed findings not herein adopted either in the form or substance proposed are rejected as not supported by the evidence or as involving immaterial matters. Having reviewed the entire record in this proceeding, including the proposed findings and briefs, the administrative law judge, based upon the entire record, makes the following:

Initial Decision

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## FINDINGS OF FACT

JURISDICTIONAL FACTS<sup>1</sup>

1. Warner-Lambert Company (Warner-Lambert), respondent herein, is a corporation organized and existing under the laws of the State of Delaware with its principal office and place of business located at Morris Plains, New Jersey.

2. Prior to November 13, 1970, when it was acquired by Warner-Lambert, Parke, Davis & Company (Parke, Davis) was a corporation organized and existing under the laws of the State of Michigan with its principal office and place of business located at Detroit, Michigan.

3. At all times relevant to this proceeding, Warner-Lambert sold and shipped, and is now selling and shipping, products in interstate commerce throughout the United States and was and is engaged in commerce as "commerce" is defined in the Clayton Act.

[3] 4. At all times relevant to this proceeding, Parke, Davis sold and shipped products in interstate commerce throughout the United States and on November 13, 1970, and prior thereto, was engaged in commerce as "commerce" is defined in the Clayton Act.

5. On November 13, 1970, pursuant to an agreement and plan of merger dated August 25, 1970, Warner-Lambert acquired ownership of all or substantially all the stock of Parke, Davis in return for 6,600,000 shares of Warner-Lambert common stock.

## RELEVANT MARKET AND LINES OF COMMERCE

6. The relevant market within which to view the merger of Warner-Lambert and Parke, Davis is the entire United States (Complaint, para. 6; Answer, para. 6; Tr. 27).

7. There are a number of lines of relevant commerce to be considered in viewing this merger. They are as follows:

(a) The overall drug market. This market consists of medicines, both pharmaceutical and biological, in dosage form and are limited in this proceeding to those for human use. Included in this market are ethical drugs and so-called proprietary drugs. Proprietary drugs are not a separate line of commerce relevant for consideration in this case, other than as a part of the overall drug market, described above. These are products manufactured and sold by the drug industry and which are promoted principally to the consuming public. They may include products for which a prescription may often be written by a physician, but which may also be sold over-the-counter without a prescription.

<sup>1</sup> The complaint alleges and the answer admits the essential jurisdictional facts. Hereafter CPF refers to complaint counsel's proposed findings and RPF to respondent's.

(b) Ethical drugs. These drugs for which a prescription from a physician is required, or which, although sold over-the-counter (OTC) without a prescription, are primarily advertised and promoted by the drug industry to the medical, pharmacy and allied professions. These ethical drugs are a relevant line of commerce for consideration in this case.

[4] (c) In addition, counsel in support of the complaint assert that there are 20 separate submarkets of the overall drug market which are included as either ethical or proprietary drugs which constitute distinct lines of commerce and must be considered individually in considering this merger. It is urged that there was either actual or potential competition existing at the time of the merger which was directly affected or eliminated as a result of the merger.

Each of these relevant markets outlined above will be treated seriatim in this initial decision.

#### ACQUIRING CORPORATION: WARNER-LAMBERT

8. Warner-Lambert's history dates back to 1856, the year in which William R. Warner founded an ethical drug business in Philadelphia (CX 43), which was acquired by Pfeifer Chemical Co. in 1908. In 1916 the stock of Richard Hudnut, a New York cosmetics manufacturer, was acquired and from 1920 to 1955 the combined business was known as Warner-Hudnut, Inc. (CX 43). Following a merger with the Lambert Company of St. Louis in 1955, the firm name was changed to Warner-Lambert Pharmaceutical Company (CX 1(B)) and in 1970 simplified to Warner-Lambert Company (CX 1(B)).

9. Between 1952 and 1970, Warner-Lambert acquired or merged with the following companies, all of whom were engaged in the broad drug market or closely allied lines of products:

<i>Date</i>	<i>Company</i>
1952	Chilcott Laboratories, Inc.
1955	The Lambert Company
1956	Nepera Chemical Company
1962	American Chicle Company
1964	Smith Brothers
1966	Texas Pharmacal Company
1967	American Optical Company
1967	Vismara Terapeutical, Sp. A
1969	Elizabeth Biochemical Laboratory

[5] Warner-Lambert, over the years, had also consistently enjoyed internal growth and expansion of a substantial nature.

10. Warner-Lambert employs 40,000 persons worldwide (CX 1(T)). The major portion of Warner-Lambert's research facilities, ethical

pharmaceutical manufacturing facilities and the executive offices are located in Morris Plains, New Jersey (CX 1(W)). Proprietary pharmaceutical products are manufactured at plants in Lintz, Pennsylvania; Rockford, Illinois; and Anaheim, California. Dermatological and hypoallergenic products are manufactured in San Antonio, Texas, and cough drops are manufactured principally in Poughkeepsie, New York (CX 1(W)).

11. In 1969, prior to the acquisition of Parke, Davis, Warner-Lambert's sales were \$808 million and total assets were \$572 million. In 1969, its total domestic sales were \$540 million and its total domestic assets were \$366 million (Complaint, para. 3; Answer, para. 3). Its sales were divided about equally between professional and consumer products and products sold internationally. In 1969, professional products, all products promoted to the medical profession, accounted for 36.1 percent of total sales, while consumer products accounted for 35.9 percent, and international sales 28.0 percent of total sales (CX 1(T)). Approximately 10 percent of the total of all sales for 1969 were accounted for by ethical drug sales (RX 2029; Tr. 2638).

12. At all relevant times, Warner-Lambert has manufactured and sold: professional products, including ethical pharmaceuticals, dental specialties, ophthalmic lenses and frames, ophthalmic and scientific instruments, sunglasses, safety products, fine chemicals and biochemical specialties.

13. Warner-Lambert over the years has enjoyed substantial growth in the drug industry, both in the ethical and proprietary portions of the drug market. The primary reasons before this growth is Warner-Lambert's ability to engage in extensive promotion (detailing) to the medical profession, including the pharmacists and related professions of its ethical drugs and the substantial advertising which it puts behind its proprietary or over-the-counter drugs. [6] Its trade name products have become very familiar to the medical profession. The advertising behind such products as Listerine, Bromo Seltzer, Super Anahist, Smith Brothers Cough Drops, Roloids have made them household names and commonly are among the leading products in their markets (CX 157, CX 222, CX 2690). In addition, Warner-Lambert has been able to use these popular trade names to sell associated products, such as tooth paste, breath spray and throat lozenges (CX 251, CX 2698).

14. Warner-Lambert utilizes every conceivable type of print and electrical medium to promote its products. These include direct mail, billboard, shelf-talkers displays, television, radio, newspapers, magazines and professional journals. In 1968 Warner-Lambert spent approximately \$80 million for domestic advertising; in 1969 approximately \$93 million and in 1970 approximately \$126 million for domestic

advertising (CX 11-12, 21, 24). In 1970 Warner-Lambert was the largest drug and cosmetic advertiser in the country and the fifth largest advertiser among all companies (CX 24, CX 289-292).

15. Warner-Lambert engages in research and development programs. In 1969 it spent approximately \$11 million for ethical research and employed about 320 persons in this endeavor (Resp. Ans., para. 3; CX 29; Tr. 2685). Warner-Lambert likewise engages in research and development work with its foreign operations and derives benefits in this country from this overseas research and development. Warner-Lambert likewise engages in research and development work in support of its proprietary drug products which amounted to approximately \$2 million in 1970 (Resp. Ans., para. 3).

16. Warner-Lambert also employs a highly capable staff of 3,000 sales representatives in the United States serving various markets. It is a highly oriented marketing company with an able promotional staff, skilled packaging experts and market planners.

17. Warner-Lambert has been successful over the years in obtaining patents on many of its products which have been well accepted in the market. In addition, Warner-Lambert is regularly engaged in licensing drugs from other companies or individuals holding patents on such drugs and at present has approximately 18 products on the market which are licensed for manufacture or sale from such companies. [7]

ACQUIRED CORPORATION: PARKE, DAVIS

18. Parke, Davis is a famous ethical pharmaceutical company (Tr. 2724) and one of the most respected names in medicine (CX 276). Since the company was founded, its research and development has resulted in hundreds of major contributions to pharmacy and medicine (CX 419). The reputation of Parke, Davis research for breadth and quality is excellent (Tr. 1840, 1886-87, 2730).

19. Parke, Davis employs approximately 15,000 persons, of whom about 7,300 are located in the United States (CX 1 (CC)). Parke, Davis' executive offices and the largest of its ethical and proprietary facilities are located in Detroit, Michigan (CX 1 (BB)). Research facilities are centered in Ann Arbor, and Detroit, Michigan, while biological products are manufactured principally at Rochester, Michigan (CX 1 (BB)). Parke, Davis owns or leases distribution centers in 23 major cities in the United States (CX 1(BB)).

20. At all times relevant to this case, Parke, Davis has manufactured and sold pharmaceutical, biological, medical-surgical and related health care products in the United States and throughout the free world (CX 1(Y)). All of Parke, Davis' pharmaceutical products were

and are ethically promoted. It had and has no proprietary products (CX 1(Z)). Pharmaceutical and biological products accounted for 41.7 percent of total Parke, Davis' sales in 1969 (CX 1(Y)), while medical-surgical products were 13.8 percent and international sales were 42.0 percent of all sales (CX 1(Y)).

21. Parke, Davis is one of the country's two "broad line" pharmaceutical companies with a "standard" pharmaceutical line designed to meet most of a physician's needs for drugs (Tr. 3581). Parke, Davis, in addition to detailing specialty items to physicians, also sells generic drugs as commodities to hospital pharmacies and drug stores (Tr. 3376, 3571-72). In 1966, Parke, Davis supplied over 700 different products in over 100 different sizes and packages (CX 412), while in 1970, Parke, Davis carried more than 1200 items in its catalogue (CX 332).

[8] 22. In the years just before merger, Parke, Davis planned to expand into proprietary markets using its broad range of consumer products (CX 330, 332, 333, 339, 363). To this end a special Consumer Products Marketing Department was established in the latter half of 1969 (CX 334, 339). However, these plans did not materialize into any entry in the proprietary field.

23. Parke, Davis in 1960 had sales of \$200 million and net earnings (after taxes) of \$30 million (CX 3710). In 1961, sales were \$184 million and net earnings were \$22 million (CX 3710). There followed two years at about the same level as 1961 after which both sales and earnings recovered slowly, reaching new peaks in 1965 and 1966 (CX 3710). In 1966, sales were \$240 million and after-tax earnings were \$32 million (CX 3710). Sales in 1967, however, remained flat and net earnings fell from \$32 to \$21 million (CX 3709-3710). There followed two years of rising sales (\$274 million by 1969) with flat earnings (\$21 million in 1969) (CX 3709). From 1965 to mid-1970 Parke, Davis' net income fell approximately 50 percent from just under \$40 million to less than \$20 million with consequent substantial reductions in dividends from \$2.25 per share in 1965 to about \$1.00 per share in the twelve-month period ending June 30, 1970, and to 60 cents in 1970 (CX 1(I)). Parke, Davis' domestic operations were worse when earnings fell from \$26 million in 1965 or 1966 to a loss of \$3 million in pre-tax earnings in 1970 (CX 360).

INDUSTRY CONCENTRATION AND MARKET SHARES IN THE OVERALL  
DRUG MARKET AND ETHICAL SECTOR

24. It is first asserted by counsel in support of the complaint that the statistical<sup>2</sup> and other relevant [9] evidence pertaining to the drug manufacturing industry as a whole and its ethical segment establish a market picture compelling a conclusion of substantial lessening of competition. It is argued that concentration among the top four and the top eight industry members show at least a loose obligarchic situation in the drug industry.

25. Set forth in the table below are the market ranks and shares in the ethical drug market and overall drug market for all firms which ranked among the top eight in any of the years 1957, 1965 or 1969. (See Appendix A attached hereto.)

ETHICAL MARKET

	1957		1965		1969	
	Rank	% Share	Rank	% Share	Rank	% Share
Lilly	1	8.54	1	6.57	1	7.37
American Cyanamid	2	6.99	7	4.34	12	2.89
American Home Products	3	6.88	2	5.82	3	6.31
Upjohn	4	6.66	5	5.24	7	4.17
Parke, Davis	5	5.96	10	4.04	11	2.90
Smith, Kline & French	6	5.74	3	5.62	8	4.17
Beechnut	7	4.94	9	4.11	9	3.66
Abbott	8	4.60	8	4.18	6	4.47
Merck & Co.	11	3.54	4	5.38	4	5.90
Roche	17	1.64	6	5.18	2	6.52
Bristol-Myers	*	*	21	1.66	5	5.10

OVERALL DRUG MARKET

Lilly	1	7.38	2	5.67	2	5.97
American Home Products	2	7.02	1	6.11	1	6.63
American Cyanamid	3	6.07	7	3.74	16	2.34
Upjohn	4	5.75	5	4.66	9	3.48
Parke, Davis	5	5.15	11	3.57	15	2.42

<sup>2</sup> The parties stipulated that Davee, Koehnlein and Keating (DKK) statistical data would "be used by both sides to establish the approximate dollar value of purchases of drugs and diagnostic materials, the break down of such purchases by product, by brand and by maker and the aggregate of all such purchases, direct or indirect, from each such maker during each of the years from 1957 through 1971, inclusive." (Stipulation Concerning Statistical Data, CC Phy. Ex. 2 at 1) They stipulated further that "such data shall be used to establish the approximate size of all product markets, both major markets and submarkets thereof, and the percentage market shares and ranks of each maker of products in such market (including Warner-Lambert and Parke, Davis)." Exceptions to this stipulation permitting the use of other data from Nielsen, U.S. Census and deHaen as well as objections to use of DKK data for certain purposes were all agreed to.



		Initial Decision				87 F.T.C.
Smith, Kline & French	6	4.96	3	5.39	6	3.92
Beechnut	7	4.27	9	3.74	11	3.17
Abbott	8	3.98	8	3.74	7	3.76
Merck & Co.	12	3.06	4	4.79	5	4.95
Roche	18	1.42	6	4.63	3	5.41
Bristol-Myers	20	1.14	15	2.18	4	5.25
Sterling	11	3.15	12	2.95	8	3.60

26. Four-firm and eight-firm concentration ratios are the ones typically examined in merger analysis. As the Commission has observed, “[E]conomists have analyzed numerous industries in terms of the four-firm and eight-firm concentration ratios.” (*Litton Industries*, Dkt. 8778, Slip Opinion, p. 46, note 34 [82 F.T.C. 793 at 1010]). Of the two ratios, the four-firm concentration ratio is probably the more significant. Thus, the Commission has held that “the traditional four-firm concentration analysis is well-suited for the purpose of merger law enforcement\* \* \*.” (*Id.*, pp. 45-46), noting that “Scherer refers to the four-firm sales concentration ratio as *the* concentration ratio” (*Id.*, p. 46, note 34, Scherer’s emphasis).

27. Based on stipulated DKK data, four-firm and eight-firm concentration in the ethical drug and all drug lines of commerce were as follows for the years 1957 through 1971:

	Ethical Drugs (RX1860)		All Drugs (RX1861)	
	CR4	CR8	CR4	CR8
1957	29.07	50.31	26.22	44.58
1958	27.82	49.17	25.43	43.78
1959	26.95	49.19	24.76	43.01
1960	25.52	46.86	23.24	41.31
1961	26.00	45.79	23.44	40.43
1962	25.35	44.14	23.38	39.77
1963	24.66	43.54	23.04	39.54
1964	23.81	42.34	22.46	38.95
1965	23.39	42.33	21.96	38.73
1966	24.35	42.75	22.74	39.23
1967	25.22	43.64	22.97	40.35
1968	25.44	43.75	22.58	38.93
1969	26.10	44.01	23.26	39.49
1970	26.29	44.43	23.80	41.38
1971	26.56	43.71	23.87	40.65

[11] 28. The record demonstrates that Parke, Davis was among the top eight manufacturers of ethical drugs until it dropped to tenth in 1964 and never recovered its position until the merger in 1970. Warner-Lambert was never among the top eight until the merger. This is also true of both companies in the overall drug market. (See Appendix A.)

Consequently, counsel in support of the complaint rely principally upon stipulated DKK statistical data for the top 20 firms in both markets for the year 1969, the year prior to the merger. This data shows the following:

Twenty Largest Suppliers of Ethical Drugs Purchased by U.S. Hospitals, Drug Stores, etc. in 1969 (CX 873)

	(\$000)	Ranks	%	App. rank as proprietary drug supplier
Eli Lilly & Co.	\$278.5	1	7.38	124
Hoffman-La Roche, Inc.	246.6	2	6.53	NA
American Home Products Corp.	238.6	3	6.32	2
Merck & Co., Inc.	223.0	4	5.91	24
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* Warner-Lambert-Parke, Davis Combined	196.8	5	5.21	5
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Bristol-Myers Co.	186.3	5	4.94	5
Abbott Labs.	169.7	6	4.50	43
Upjohn Co.	157.8	7	4.18	34
Smith, Kline & French Labs	157.7	8	4.18	10
Squibb Beech-Nut, Inc.	138.3	9	3.66	20
Pfizer, Inc.	126.7	10	3.36	11
Parke, Davis & Co.	109.5	11	2.90	44
American Cyanamid Co.	109.4	12	2.90	83
G.D. Searle & Co.	94.6	13	2.51	909
Schering Corp.	89.3	14	2.37	23
Warner-Lambert Pharmaceutical Co.	87.3	15	2.31	4
Johnson & Johnson	86.9	16	2.30	9
Sterling Drug, Inc.	85.5	17	2.26	1
A.H. Robins & Co., Inc.	79.3	18	2.10	22
Sandoz-Wander, Inc.	76.6	19	2.03	NA
Ciba	75.3	20	2.00	27
All other suppliers	956.8		25.36	
Total purchases of drugs— U.S. Hospitals, Drug Stores, etc.	3,773.7		100.00	

Twenty Largest Suppliers of all Drugs Purchased by U.S. Hospitals, Drug Stores, etc., in 1969 (CX 874)

	(\$000)	Rank	%
American Home Products Corp.	\$309.7	1	6.63
Eli Lilly & Co.	278.8	2	5.96
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* Warner-Lambert — Parke, Davis Combined (Assuming merger in 1969)	256.4	3	5.49
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	Initial Decision		87 F.T.C.
Hoffman-La Roche, Inc.	252.6	3	5.40
Bristol-Myers Co.	245.7	4	5.26
Merck & Co., Inc.	231.4	5	4.95
Smith, Kline & French Labs.	182.7	6	3.91
Abbott Labs.	176.3	7	3.77
Sterling Drug, Inc.	168.4	8	3.60
Upjohn Co.	162.6	9	3.48
Pfizer, Inc.	150.6	10	3.22
Squibb Beech-Nut, Inc.	148.0	11	3.17
<i>Warner-Lambert Pharmaceutical Co.</i>	143.5	12	3.07
Johnson & Johnson	118.2	13	2.53
<i>Parke, Davis &amp; Co.</i>	112.9	14	2.42
American Cyanamid Co.	110.1	15	2.36
Richardson-Merrell Inc.	108.6	16	2.32
Schering Corp.	97.8	17	2.09
G.D. Searle & Co.	94.6	18	2.02
A.H. Robins & Co., Inc.	87.9	19	1.88
Ciba	81.8	20	1.75
All other suppliers	1,411.8	—	30.21
Total purchases of drugs- U.S. Hospitals, Drug Stores, etc.	4,674.0	—	100.00

[13] 29. Based on stipulated DKK market data, the shares and ranks of Warner-Lambert and Parke, Davis in the two years preceding the merger were as follows:

ETHICAL					
	<i>Warner-Lambert</i>		<i>Parke, Davis</i>		
	<i>Share</i>	<i>Rank</i>	<i>Share</i>	<i>Rank</i>	
1968	2.41	14	2.93	12	(RX 1822)
1969	2.31	15	2.90	11	(RX 1824)
ALL DRUGS					
1968	3.08	12	2.43	14	(RX 1852)
1969	3.10	12	2.42	15	(RX 1854)

Based on the same industry source, the merged firm's post-merger shares and ranks in 1970 and 1971 were as follows:

	<i>Ethical Drugs</i>			<i>All Drugs</i>		
	<i>Share</i>	<i>Rank</i>		<i>Share</i>	<i>Rank</i>	
1970	5.05	5	(RX 1826)	5.47	4	(RX 1856)
1971	4.81	5	(RX 1828)	5.27	4	(RX 1858)

30. Counsel in support of the complaint gloss over all of the statistical data in the record as to the market structure and heavily emphasize the 20 submarkets and the concentration statistics involved in each of those submarkets. However, they do request findings that

there is substantial concentration both in ethical drugs and all drugs and that therefore the merger here involved furthered such concentration. The stipulated statistics of record will not support such findings. These tables show that there has not been a constant group of firms comprising the top four and top eight of either the ethical drug or all drug lines of commerce. In the ethical drug market, no less than eight firms have ranked within the top four, while 11 different firms have been within the top eight. Similarly, in the all drug market, nine firms have been in the top four, with 12 different firms having ranked eighth or higher. The change in composition of the leadership group reflects substantial risings and fallings of individual firms. For example, [14] in the ethical drug sector, two of the top four firms in 1969, Merck and Roche, had ranked 11th and 17th, respectively, as recently as 1957. Conversely, American Cyanamid and Upjohn, which ranked second and fourth, respectively, in 1957 had dropped to 12th and 7th positions by 1969.

31. The industry leaders have not been able to maintain or expand their market shares. With respect to the ethical line, the top four companies collectively accounted for 29.07 percent of sales in 1957. By 1969, the collective share of these former leaders had shrunk by nearly one-third to 20.74 percent. The same is true for the all drug line, with the 26.22 percent collective share of the four 1957 leaders having dropped to 18.42 percent by 1969. Moreover, without exception, each of the top eight ethical drug manufacturers in 1957 lost market share during the succeeding years. In some cases, such loss was very substantial. American Cyanamid, for example, dropped from 6.99 percent in 1957 to only 2.89 percent in 1969; Upjohn fell from 6.66 percent to 4.17 percent; and Smith, Kline & French dropped from 5.74 percent to 4.17 percent. Although the percentages differ, the universal loss in market share by the leading companies was also true in the all drug line of commerce.

32. Parke, Davis is a good example of a once leading firm that was unable to maintain its market share and rank. In 1950, Parke, Davis ranked second in the drug industry (Tr. 2294-98). Ten years later, in 1960, Parke, Davis was still an industry leader, ranking third in the ethical drug line with 6.02 percent of sales (RX 1806), and fourth in the all drug line with 5.08 percent of sales (RX 1836). By 1969, Parke, Davis had dropped to 11th position in ethical drugs and 15th in the all drug line, with a market share in each line well below 3 percent. In 1971, the year after the merger, the Warner-Lambert/Parke, Davis combined ethical drug share was 4.81 percent (RX 1863 Revised) which is less than Parke, Davis alone accounted for ten years earlier (*id.*).

[15] 33. These statistics in and of themselves establish that there is

no "interdependence" in the drug industry (Tr. 2184-85, 3790-92). In fact since the drug industry is characterized by important changes in market share and rank, it cannot be said to fit the oligopoly theory. Such changes indicate independent rather than interdependent market behavior (Tr. 3791-93).

34. Counsel in support of the complaint urge that there has been a marked trend towards concentration in the drug industry citing Bureau of Census data showing a gross decline in the number of firms from 1143 in 1947 to 791 in 1967. This Census information is somewhat dubious as a result of the manner in which the Census Bureau classifies companies within an industry according to their principal line of business. There are also stipulated DKK data in the record which show that there were more than 1400 companies in the overall drug market and 800 in the ethical sector alone in 1969 and 1970 (CX 727; RX 2028-44). Consequently, the record contains no credible evidence that a trend toward concentration has taken place in the industry.

35. The cases upon which counsel in support of the complaint rely are not in point,<sup>3</sup> particularly in view of the Commission's analysis of these cases in *Sterling Drug, Inc.*, 80 F.T.C. 477,597-98 (1972). In all of these cases there was a finding of a steady tendency toward concentration in the industry involved or that the acquisition noticeably increased the market share of the first or second top firm which already controlled more than 20 percent of the market. As the Commission pointed out, something more than mere "horizontalness" must be shown. Even the horizontalness of the merger here involved is minimal involving two companies which certainly are in the "drug" industry. However, Parke, Davis' sales are limited to sales in the ethical sector of the drug industry [16] and only about 10 percent of Warner-Lambert's sales fall into the ethical sector. Ninety percent of Warner-Lambert's sales are in the proprietary drug market and none of Parke, Davis' sales were made in this market. In addition, Parke, Davis concentrated on drugs sold to the ethical sector of the market on a generic basis while Warner-Lambert's sales in the ethical market were concentrated on specialty items promoted to that market. Even in the submarkets, hereafter discussed, in which it is claimed the substantial existing or potential competition has been eliminated, serious problems arise, not only as to proper market definition and the nature of the competition between the companies, but also as to the significance of the total sales of these products by the two companies. It is estimated that total sales by the two companies in these 20

<sup>3</sup> *United States v. Von's Grocery Co.*, 384 U.S. 270 (1960); *United States v. Pabst Brewing Co.*, 384 U.S. 546 (1966); *United States v. Aluminum Co. of America*, 377 U.S. 271 (1964); *United States v. Continental Can Co.*, 378 U.S. 441 (1964); *United States v. Philadelphia National Bank*, 374 U.S. 321, 363 (1963).

submarkets could amount to no more than 1 percent of total industry sales of all drugs (CX 902,3457, 1862,2042,2360).

36. Counsel in support of the complaint argue that this merger must be examined in the light of the "powerful" barriers to new entry in the drug industry. They urge that these barriers consist of the need to undertake substantial R&D activity; the burdens imposed by FDA regulation; the exclusionary effect of patents, and product differentiation arising from the use of trade names; the impact of anti-substitution laws, and the employment of various ethical and proprietary drug promotional techniques.

37. R&D activity and the necessity for meeting the FDA regulation burdens are closely related since the R&D expenditures and activities are all directed toward an attempt to obtain FDA approval of new drugs. Both Warner-Lambert and Parke, Davis recognize the importance of R&D and both expend substantial amounts of money for ethical drug research and development. In 1970, Parke, Davis expended \$21 million and Warner-Lambert \$14 million on ethical drug research for a worldwide total of \$35 million. Based upon a survey in 1970 by the Pharmaceutical Manufacturers Association (PMA), \$611 million was spent by that Association worldwide. This gives Parke, Davis a 3.4 percent share in 1970 and Warner-Lambert a 2.3 percent share for a combined share of 5.7 percent. Counsel in support of the complaint urge that R&D is highly concentrated in the drug industry. For example, based upon Commission Exhibit 3187, they urge that the first four companies account for 42 percent of total R&D expenditures in 1970; the first eight, 61 percent, and the first 20, 91 percent. The [17] difficulty with these figures is that there is nothing in the record which will provide a basis for a finding that the combination of Parke, Davis and Warner-Lambert had any significant effect upon these figures in 1970. New chemical entities (NCE's) are recognized in the industry as one of the indicators of successful R&D effort (Tr. 2321). During the period 1965 to 1972, Parke, Davis is credited with three NCE's and Warner-Lambert with two (RX 419, 420, 442). However, both the NCE's of Warner-Lambert were developed by other companies (RX 434) and one credited to Parke, Davis was developed by Schering (RX 450). It can only be concluded that Warner-Lambert's and Parke, Davis' combined share would be insignificant at approximately 3.9 percent. There is nothing in the record from which to conclude that the combination of Parke, Davis and Warner-Lambert in any way heightened the barriers to entry into the drug industry or any of its product submarkets because of the necessity to undertake substantial research and development work in that industry.

38. Prior to the Food and Drug Act amendments of 1962 only the

safety of a drug had to be proven before marketing and this was done without FDA supervision. The amendments of 1962 required that both the safety and efficacy of a drug be proven by tests, supervised by FDA, on humans as well as animals (Tr. 2395-96,2752-54). Now it is necessary to obtain a claimed investigational new drug exemption, or IND, which allows a firm to proceed with human studies. Detailed disclosures about the drug and the manner in which the drug is being tested are required. Studies of the drug in animals must be made and studies in humans are subject to strict regulations and close FDA supervision. All of the information gathered in these studies is submitted to the FDA in the form of a new drug application (NDA) (Tr. 2822). A substantial amount of information is required by the FDA and is very carefully, even stringently, checked by the FDA before a new drug application will be granted. All of this effort is a part of R&D expenditures discussed above. The FDA has established a different method of approval of drugs which have the same chemical composition of drugs which were on the market between 1938 and 1962. This is called an Abbreviated New Drug Application (ANDA). [18] Under this procedure, a new manufacturer of drugs of established efficacy has only to demonstrate the adequacy of his manufacturing facilities, his methods for determining that the proper amount of drug is in the dosage form, and the bioavailability of the drug. This procedure has greatly reduced the cost of obtaining approval for marketing of new drugs, particularly generic drugs. This abbreviated procedure has been widely employed by many companies and hundreds of ANDAs for numerous products have been awarded (RX 393-414; Tr. 2766-70, 3581-84). While the new procedures and regulations required by the 1962 amendments to the Food and Drug Act have substantially increased the work and cost of marketing new drugs, there is nothing in the record which will permit a finding that the additional cost and effort was in any way heightened as a result of the merger here involved or that the merger in any way heightened the barriers to entry into the drug industry or any of its product submarkets. Nor is it possible to conclude that the new Warner-Lambert, Parke, Davis R&D combination will be in a position to adversely affect any other drug company's R&D programs.

39. Patents play an important competitive role in the drug industry since the holder of a patent on a drug or process for making a drug has an exclusive 17-year right to make and sell or to license whomever they wish to make or sell the drug. A patentholder usually attaches a trade name to any drug on which he may have a patent in addition to the generic name for such drug. Thereafter, the drug is promoted and detailed to the physicians and pharmacists using the trade name and

an attempt is made, often successful, to differentiate this drug in the mind of the prescribing physician from any other firm's drug. In this area anti-substitution laws also play a part since virtually every state by law or Pharmacy Board regulation requires the pharmacist to fill a prescription exactly as written by the physician. Consequently, these laws attach a peculiar value to trade names in the business (Tr. 2234-35, 3471). This is particularly true in the ethical drug market. While all this is true, there is nothing in the record to establish that the existence of these facts were in any way enhanced or changed as a result of the merger here involved. Neither Parke, Davis nor Warner-Lambert can be held responsible for the existence [19] of the patent laws and nothing in the record will permit a conclusion that the combination of the two has in any way enhanced the effect of the patent laws or product differentiation in the ethical drug market. In addition, as a result of recent pressures more and more drugs are being prescribed or purchased under their generic names which permits a pharmacist to fill the prescription with whatever company's drug he has on hand (CX 3688). Parke, Davis had a patent on the drug chloramphenicol which it sold under the trade name chloromycetin. This patent expired in 1966 and other companies are now selling chloramphenicol. However, Parke, Davis still maintains the leadership in chloramphenicol with 94 percent of total sales (CX 4008). This drug accounted for more than 20 percent of Parke, Davis' total sales as recently as 1967 (CX 1 (Z)). However, this drug had developed serious and oftentimes fatal side effects resulting in adverse publicity and its sales had declined substantially accounting at least in part for the difficulties that Parke, Davis found itself in prior to the merger. There is no other evidence that Parke, Davis or Warner-Lambert had any significant patent control of any drug which could be enhanced by this merger.

40. In the 20 submarkets upon which counsel in support of the complaint rely and which are discussed hereafter, patents do not appear to play any significant role. Product differentiation is more a product of drug promotion, particularly detailing and there is nothing in the record which will support a finding that product differentiation was in any way affected by the merger here involved. Anti-substitution laws appear to serve the function of protecting the physician and his patient and are in no way enhanced as a result of the merger here involved. In any event the policy of patent protection for a discoverer of a new drug with the resulting lack of competitive ability by others is clearly an exception to the antitrust laws if the patent is legally obtained.

41. Counsel in support of the complaint urge that the merger has eliminated Parke, Davis as one of the leading drug companies because



of its ability to promote products ethically to the medical profession. Promotion to the medical profession which includes physicians, pharmacists and all types of hospitals, is done by means of detail [20] calls by drug company salesmen, advertising in various medical journals and direct mail to the medical profession. Counsel in support of the complaint emphasize that Parke, Davis had 900 men in its detail force and that detailing, journal advertising and direct mail circulation was highly concentrated among the top 20 firms in the industry. The evidence as to the rank and share of the various members of the industry are contained in the *in camera* file and are Commission Exhibits CX 3601-24. This evidence shows that Warner-Lambert and Parke, Davis were each very small in their percentage rank in all types of ethical promotions even when combined. Their ethical promotions, however measured, account for a smaller percentage share in each category than it does of their combined ethical sales with one exception. There is no evidence that any one or two firms had a percentage in ethical drug promotional activity anywhere approaching 20 percent or that this type of activity was highly concentrated at the four firm or eight firm level. Counsel in support of the complaint again emphasize that the 20 firm level of concentration is quite highly concentrated but there is no firm in any sort of a dominant position. This evidence will not permit a finding that the combination of Warner-Lambert and Parke, Davis will adversely affect the competitive situation in the drug industry insofar as it pertains to promotional activity in the ethical sector. In the proprietary sector, Warner-Lambert is a major consumer advertiser of both proprietary drugs and nondrug products (CX 11-12, 70). In 1970, it ranked fifth among the top 100 advertisers according to *Advertising Age* data (CX 287-288). Parke, Davis engaged in no proprietary advertising and there is no credible evidence that it would ever become a significant proprietary drug marketer (CX 1 (Z)). Consequently, the merger will have no effect upon promotional activities for proprietary drug products.

42. Counsel in support of the complaint urge that the evidence showing the high level of profitability in the drug industry is indicative that there are substantial barriers into entry into the drug industry. The evidence upon which counsel in support of the complaint rely consists of a number of the Commission's Quarterly Financial Reports (QFR's) and the testimony of their economic expert (Tr. 2194-97, 2207). These annual rates of return on stockholders' equity in the drug industry range from 16.8 percent to 20.3 percent for the drug industry as compared with 8.6 percent [21] to 12.3 percent for all manufacturing on the average (Tr. 2197-98). From this, it is argued that entry barriers in the drug manufacturing business must be formidable (Tr.

2200). The problem with the Commission's QFR's is that they fail to deal adequately with advertising and R&D costs that are "expensed" rather than "capitalized" as a part of the stockholders' equity in the drug industry. The Commission itself has pointed out these deficiencies in its Statement of Purpose accompanying Annual Line of Business Report Program Proposal, August 1972, p. 6:

[E]xpensing [of advertising costs] usually results in a measurement of the rate of return on capital which is higher than if such costs were capitalized. \* \* \* As with sales promotion costs, the expensing of R&D costs usually leads to an overstatement of profitability, with the overstatement increasing with the intensity of R&D effort.

As a result the argument of counsel in support of the complaint is based upon evidence which is quite unreliable and possibly meaningless, particularly for an industry with large R&D expenditures and sales promotion costs such as the drug industry. Consequently, the proposed findings of counsel in support of the complaint in this regard are rejected.

43. Contrary to the contentions of counsel in support of the complaint, there have been a number of successful new entrants into the drug industry both by domestic and foreign companies, many of these entries have been subsequent to the enactment of the 1962 amendments to the Food and Drug Act. Among these are Marion Laboratories (Tr. 3663-73; RX 1827, 1862 Rev. A, 2387-88), S.J. Tutag Company (Tr. 3684-3703), Rachele Laboratories (Tr. 1747-49, 1669-76). Other examples are Reid Provident Laboratories (Tr. 3699-3700), Rucker Pharmaceutical (Tr. 3679, 3699), McKesson Laboratories (Tr. 1851-1861, 1863), Rorer (Tr. 3884-85; CX 3365-69), Syntex (Tr. 3385, 3665-69), Flint (Tr. 3386). In addition, E.I. du Pont has entered the drug industry with the purchase of Endo in 1969. Minnesota, Mining and Manufacturing Company has entered the ethical drug business by acquiring the Riker Company in 1970 (Physical Exh. 2, Appendix A; CX 3367). A number of foreign pharmaceutical [22] companies have entered the United States drug market and four presently rank among the top 20 U.S. ethical drug manufacturers, Roche, Ciba-Geigy, Sandoz and Burroughs-Wellcome (RX 1862 Rev. A). There are likewise a considerable number of foreign firms who have entered the United States market recently generally by acquisition of a small American drug firm (Tr. 3377-79, 2992-93, 3380-81, 3442, 2829, 3382-83).

44. Counsel in support of the complaint have submitted a large amount of testimony and exhibits attempting to establish that the acquisition has had substantial adverse effects in 20 submarkets of the drug industry. These are as follows:

1. Thyroid Preparations

2. Anti-Anginal Drugs
3. Cough Remedies
4. Cough Drops and Lozenges
5. Cold Remedies
6. Oral Decongestants
7. Antihistamines
8. Bronchial Dilators
9. Antacids
10. Irritant Laxatives (Ethical)
11. Emollient/Protective Dermatological Preparations
12. Prenatal Vitamins
13. Antibiotics Useful Against Gram-Negative Bacilli
14. Ampicillin
15. Anti-Pseudomonas Drugs
16. Urinary Antibacterials (non-sulfa)
17. Mouthwash
18. Normal Serum Albumin
19. Immune Serum Globulin
20. Tetanus Immune Globulin

These drugs purport to be defined in terms of therapeutic end use and correspond approximately to 7-digit Standard Industrial Classification (SIC) categories (Tr. 2357-59). Counsel in support of the complaint assert that either Warner-Lambert or Parke, Davis was a potential entrant into these product markets or was an existing manufacturer in these markets and was eliminated as either a potential or existing competitor and consequently there has been a substantial lessening of competition in each market as a result of the merger.

[23] 45. In five of these submarkets; namely, anti-anginal drugs, emollient/protective dermatological preparations promoted ethically, bronchial dilators, urinary antibacterials (non-sulfa) and antacids (ethical), the share of the market represented by drugs sold by Parke, Davis in each instance accounted for less than one percent (RX 1766,1664,1758; CX 2620,1879) of the products sold in that submarket. As a result, it is concluded that Parke, Davis' market share in each of these alleged submarkets is so small that the elimination of Parke, Davis as a potential future competitor of any significance must be rejected. Parke, Davis had been in these markets for a number of years and had never improved its market position and the record contains no credible evidence that such might occur in the future. In addition, the record contains substantial evidence that there are a large number of companies both large and small in each of these five submarkets who

are at least as capable as Parke, Davis of increasing their share of these markets despite the fact that their shares remained small (RX 1665,1760, 1768,1778,1719,1716).

46. Three of these submarkets relied upon by counsel in support of the complaint; namely, antacids, cough drops and lozenges and mouthwash, are essentially proprietary drugs since their principal sales are directed to the consumer and require, for effective selling, expertise in media advertising and a developed system of distribution to all classes of trade (Tr. 3208,3215,3637,3522). Parke, Davis had none of these qualifications essential to be an effective proprietary drug marketer in the foreseeable future. As found above, the Parke, Davis market share in antacids was about 0.1 percent. In cough drops and lozenges, Warner-Lambert was among the leading companies with about a 26.8 percent share (CX 1463-64). Parke, Davis had less than 3 percent of the market with outmoded products and consequently lacked any significant competitive potential. In mouthwash products, Warner-Lambert is the clear leader with about 50 percent of the mouthwash market, accounted for principally by its Listerine antiseptic mouthwash (CX 2688). Parke, Davis had four mouthwash products which in 1970 had *de minimis* total sales of \$29,000 (CX 2688). Again mouthwash sales are primarily a proprietary item and there is nothing in the record to indicate that Parke, Davis could have become any sort of a significant competitor in [24] this market in the foreseeable future. As pointed out above, the Commission's decision in the *Sterling Drug, Inc.* case will not permit a finding of substantial lessening of competition upon a mere showing of horizontality between the two firms involved in the merger as is contended by counsel in support of the complaint. The market shares of Parke, Davis here involved are so insignificant that they will not permit the mechanical application of a horizontality rule. Something more must be shown and the record is lacking in this respect. The contentions of counsel in support of the complaint that there could be any substantial lessening of competition in the seven submarkets discussed above are rejected.

#### PRODUCT SUBMARKETS

47. *Thyroid Preparations.* Parke, Davis markets only unbranded thyroid: thyroid USP, marketed in several grainage doses (Tr. 645; CX 923), and a variation thereof, thyroid strong, which contains 50 percent more iodine per grain than USP (Tr. 646; CX 924). Warner-Lambert markets only branded thyroid: the nonsynthetic, purified product Proloid (Tr. 646; CX 913-14), and a synthetic T-4/T-3 combination, Euthroid (Tr. 646; CX 915-16). All of these products are used for the treatment of "Hypothyroidism," which is the condition resulting from

undersecretion by the thyroid gland of thyroid hormone, a substance having as its principal function the regulation of metabolic processes and rates within the body (Tr. 629-30). Complaint counsel urge that all thyroid preparations, including both branded and unbranded products, comprise a single line of commerce for Section 7 purposes. Respondent disputes this, contending that unbranded and branded thyroid preparations compete in separate economic submarkets.

48. There are substantial differences in the way the two companies' products are manufactured, the customers and methods used in selling their products, the way they are priced, and since they are sold only on prescription of a physician, the way they are dispensed to the ultimate user. USP thyroid is produced by taking the thyroid glands from slaughtered pigs or cattle, removing extraneous tissue and cleaning and drying the remainder (Tr. 631). Proloid, on the other hand, is obtained from a purified extract of frozen hog thyroid (CX 913). The synthetic brands are synthesized by chemical laboratory processes (Tr. 631). [25] USP thyroid is an unbranded generic product. As such, it is a "commodity" item whose sales effort is directed to the pharmacist and not to the physician (Tr. 3397, 3014, 3130). This is because the decision as to which brand of USP thyroid will be used to fill a USP prescription resides with the pharmacist, since physicians do not ordinarily specify a brand when they write USP prescriptions. The pharmacist will generally purchase the USP product with the lowest price, assuming quality is comparable (Tr. 3017-18). He cannot use either Warner-Lambert's Proloid or one of the branded synthetics to fill USP prescriptions (Tr. 3018). Branded thyroid products are promoted to the physician in an effort to secure their brand name specification on thyroid prescriptions (Tr. 3397, 3130). The prices of the unbranded USP thyroid products are set without any regard to the prices for the branded thyroid products whether natural or synthetic (Tr. 3130-31, 3157-58). This is because of the manner in which the products are promoted and dispensed. The prices of branded thyroid products are likewise set without any regard to the prices of the USP products (Tr. 3392-94). However, it all really depends upon the physician and what he prescribes. Natural USP has been on the market since the 1930's and many physicians have had experience with this product and continue to prescribe it because it is a good product with which they are familiar. The branded natural and the synthetics appear to have a small advantage over the USP in that the active components are more exact and therefore can yield a somewhat more accurate result in laboratory tests on a patient's blood samples. This advantage is at best marginal and is generally discounted by the

medical profession as having any real significance (Tr. 3368,879, 881,335-54,877,3398).

49. The merger in no way strengthens Warner-Lambert's hand in the alleged thyroid market, since there is no advantage to Warner-Lambert in including in its line a USP thyroid product in addition to its branded products Euthroid and Proloid. USP thyroid competes in the generic commodity market in the retail pharmacy. The Warner-Chilcott Division, on the other hand, is a specialty house which markets its brand name products to the physicians. Had it found the USP thyroid market desirable, Warner-Lambert could have entered long ago, since hog and beef thyroid was readily available to it (Tr. 3397).

[26] The record also shows that there are apparently no barriers to entry into the thyroid preparations field and that there are 37 companies in the field with a substantial number of new entrants in recent years (Tr. 874-75; RX 1716-18).

50. It is concluded that there are significant differences between the two types of thyroid products sufficient to preclude the lumping of them together as a line of commerce with any real commercial significance. The thyroid market is highly concentrated with four companies being the leaders with Warner-Lambert ranking third with 20.8 percent of sales in 1970. Combined Warner-Lambert and Parke, Davis have 25.4 percent of the market and rank number one. However, this small increase in concentration in the overall thyroid market must be discounted because of the insignificant impact of the combination in the market found above.

51. *Cough Remedies.* A cough can be treated either by removing the foreign particle or curing an infection in the respiratory tract or by treating the cough itself symptomatically. Symptomatic treatment, with which we are here involved, can be accomplished by relieving the irritation locally or by suppressing the cough reflex in the brain. Materials which act locally are demulcents, local anesthetics and expectorants. Antitussives act on the brain or central nervous system to inhibit the cough reflex. Demulcents are soothing, syrupy or sugary substances. Local anesthetics reduce the pain or irritation causing the cough. Expectorants induce secretions in the lung which wash out the irritant, soothing the irritated area making the mucous in the tract thinner so that it can be coughed out. There are three physical forms in which cough remedies are manufactured: (1) liquid syrups, (2) tablets and capsules, (3) cough drops and lozenges. The liquid preparations can contain antitussives, expectorants, demulcents or any combination of these. Tablets or capsules can contain antitussives and expectorants but have no demulcents therein. Cough drops and lozenges always contain a demulcent which may be accompanied by antiseptics,

anesthetics or antitussives or any combination of these (Tr. 743-754, 3713-16).

[27] 52. Cough remedies are marketed as either proprietary or ethical products. Of the ethical products, some are available by prescription only while others can be purchased by consumers, so-called ethical OTC drugs (Tr. 3631-32; RX 1797). There is a definite distinction between cough drops and lozenges compared to cough syrup. All cough drops and lozenges are usually self-medication by the consumer. They can be bought cheaply almost anywhere and carried in one's pocket or purse (Tr. 915). For a persistent cough which requires the attention of a physician, a cough drop or lozenge is virtually never prescribed or recommended (Tr. 3632-33, 3717, 1701). A physician would prescribe an ethical product with which he was familiar and this would more than likely be a syrup with more active ingredients (Tr. 905, 3645-46).

53. The liquid cough preparation submarket (including similarly-acting capsules and tablets) had 1970 total sales of \$107,488,000. Parke, Davis had an 8.3 percent share in this market in 1970, based on its prescription and ethical OTC cough syrups. Warner-Lambert had a *de minimis* 0.59 percent market share, based primarily on its cough/cold combination, Nilcol, plus several minor proprietary syrups (RX 1797). Warner-Lambert's market share declined to approximately 0.02 percent by 1973 due to the failure of Nilcol.

54. Counsel in support of the complaint contend that all products useful against coughs are part of this submarket. Respondent takes the position that all cough remedies cannot be placed in one submarket since there were substantial differences in ingredients, usage, promotion, customers and prescription status. Over 95 percent of Warner-Lambert's sales of cough remedies are of cough drops and lozenges sold as proprietary drugs, while over 83 percent of Parke, Davis' factory sales are of ethical cough syrups, 60 percent being the prescription syrups Ambenyl and Benylin. It thus appears that it would be improper to lump all cough remedies together as a submarket for Section 7 purposes. In fact, counsel in support of the complaint apparently recognize that there is a distinct cough drop and lozenge submarket since it is one of the twenty submarkets which they say has been adversely affected as a result of this merger.

[28] 55. In any event, if an overall cough remedy market is recognized, Warner-Lambert had 3.6 percent of such market in 1968 and 4.4 percent in 1969, while Parke, Davis had 4.1 percent in 1968 and 4.4 percent in 1969 (CX 1461). The market is only moderately concentrated, with four-firm concentration in 1969 at 44.9 percent and eight-firm concentration at 62.0 percent (CX 3457). Included in the

market are a total of 188 firms marketing cough remedies in 1969-1970, including 41 of the top pharmaceutical companies and all of the top 20 (RX 1786-96). The record contains no evidence that there is any barrier to entry into the cough remedy market and the record will not support a finding that the merger of Warner-Lambert and Parke, Davis in the cough remedy market will result in any substantial lessening of competition in that market.

56. *Cold Remedies*. Since there is no cure for the common cold, treatment is directed at relieving the unpleasant symptoms, *i.e.*, "rhinitis." Other symptoms may also include a sore throat, fever, malaise and cough (Tr. 756-58).

57. Warner-Lambert marketed five cold remedies in 1969 and 1970: Sinutab, Super Anahist Tablets, Sinubid, Listerine Cold Tablets and Nilcol (CX 1495, 1649, 1650, 1652). Parke, Davis marketed three cold remedies in 1969 and 1970: Coryza RX A, Richards CCT tablets and Rhinitis Full Strength CCT tablets and Cosanyl-DM Cough Syrup (CX 1701). In addition, counsel in support of the complaint assert that Parke, Davis' prescription cough syrup Benylin Expectorant and Ambenyl Expectorant are cold remedies. This claim must be rejected. First, counsel in support of the complaint have previously classified these drugs as cough remedies. Their argument that the fact that these products contain antihistamines make them cold remedies must be rejected. The FDA's Interim Guidelines on Cough and Allergy Products state that antihistamines "alone or in combination [are] not considered as safe and effective for relief of the symptoms of the common cold." (CX 3235) This confirms all the modern teaching on the subject of effectiveness of antihistamines (Tr. 764). In addition, it appears that Benylin and Ambenyl are promoted solely as cough remedies (Tr. 3308-10, 3586; RX 1515-17). Further, in a later proposed finding (421), counsel in support of the complaint apparently conceded that oral decongestants are the most accepted therapy for the treatment of colds.

[29] 58. Warner-Lambert's position in the cold remedies market fell from 9th in 1969 to 10th in 1970, although in both years it accounted for approximately 4 percent of the market. Since Ambenyl and Benylin are not cold remedies, Parke, Davis' share of the cold remedies market is *de minimis*. Its Coryza and Rhinitis tablets, both over 30 years old, had combined 1970 factory sales of \$14,000. Their sales decreased at an annual rate of 10 percent during the four previous years (CX 1652). Its Cosanyl-DM Cough Syrup (Improved Formula), containing the decongestant phenylephrine and the antitussive dextromethorphan, was introduced on September 1, 1970 (CX 1701). Its annual factory sales appear to be approximately \$214,000 (calculated from CX 1472). DKK



reports 1970 sales of Cosanyl-DM generally (presumably including the old nondecongestant formula) of \$368,000 (CX 1753). According to DKK, Parke Davis had 0.04 percent of the cold market in 1969 and — using the \$368,000 figure for Cosanyl-DM — 0.16 percent of that market in 1970 (RX 2046). Even with Ambenyl and Benylin included, Parke, Davis' market share would have been only 2.0 percent in 1969 and 2.3 percent in 1970 (CX 3463).

59. Even if Benylin and Ambenyl were to be considered cold remedies, the combination of Warner-Lambert's four percent and Parke, Davis' two percent share would have no substantial anticompetitive effect in this market. Concentration in the cold remedies market is at a moderate level and is declining. Four-firm concentration in the market declined from 46.98 percent in 1969 to 44.80 percent in 1970, while eight-firm concentration decreased from 70.09 percent to 69.03 percent (RX 2045). Market shares are well distributed. In both 1969 and 1970, seventeen firms had more than one percent of the market (RX 2045-46). Also, the number of firms in the market is both large and constant. In both 1969 and 1970, 224 companies marketed cold remedies (RX 2045-59).

60. It is concluded that the acquisition of Parke, Davis will not have the effect of substantially lessening competition in the cold remedy submarket.

61. *Oral Decongestants.* Oral decongestants are Sympathomimetics useful in relieving the rhinitis associated with the common cold. Oral decongestants are swallowed and enter the blood stream through the stomach. They can have [30] dangerous side effects elsewhere in the body and the dosage must therefore be limited. There are also topical decongestants, such as sprays which are useful but may not reach as deeply as the oral preparations (Tr. 760-62).

62. In 1969, Warner-Lambert ranked 9th in the oral decongestant market with a 5.15 percent market share. In 1970 it ranked 8th with 5.19 percent (RX 2060). Smith, Kline & French Laboratories are the leading marketer with 20 percent of the market, the remaining seven of the top eight range from 8 percent to Warner-Lambert's 5.19 percent. Parke, Davis entered this market in 1970 with sales of Cosanyl-DM cough syrup of \$368,000 which represents 0.18 percent of the market (CX 1753; RX 2061). The oral decongestant market is not highly concentrated with the four-firm concentration at 43.76 percent in 1969 and 44.02 percent in 1970, the eight-firm concentration at 70.06 percent in 1969 and 70.30 percent in 1970. The record shows that there are a large number of firms in the market — 191 in 1969 and 189 in 1970. Barriers to entry must be found to be low and among those firms

which, like Parke, Davis had less than one percent of the market, were 23 of the top 50 firms and eight of the top 20 firms (RX 2060-72).

63. Parke, Davis' entry into this market in 1970 must be considered *de minimis* and in view of the lack of concentration in the market and the large number of firms in this market, the record provides no basis for a finding that the acquisition of Parke, Davis may be to substantially lessen competition in the oral decongestant submarket.

64. *Antihistamines*. The primary purpose and single-ingredient of antihistamines is to allay the effects of allergic reactions associated with histamine release in the body, such as high fever, food allergy, animal dander and insect stings. All single-ingredient antihistamines produced by the various manufacturers have a similar effect on the body, serve primarily the same therapeutic purpose, are substantially interchangeable and have the same basic side effects (Tr. 773-76). Antihistamines are a proper submarket for Section 7 purposes.

[31] 65. The antihistamine market is highly concentrated with the top four firms accounting for 74.6 percent of sales in 1969 and 74.4 percent in 1970 and the top eight firms accounting for 95.4 percent in 1969 and 95.3 percent in 1970 (CX 1755). Parke, Davis is the second largest seller of single-ingredient antihistamines, accounting for 21.9 percent of sales in 1969 and 23.2 percent of sales in 1970. In addition to the top eight firms, there are 47 other firms in the antihistamine market, accounting for approximately 4.4 percent of that total market. Warner-Lambert no longer markets a single-ingredient — antihistamine. Its product was discontinued in 1969 when its sales had fallen to \$3,000 (Tr. 3407; CX 1801-02; RX 1694).

66. Counsel in support of the complaint urge that Warner-Lambert was a likely company to reenter the single-ingredient antihistamine market since it had filed five single-ingredient antihistamine product Abbreviated New Drug Applications (Tr. 3408-09, 3516; CX 3626-28). The record shows that many other companies also filed Abbreviated New Drug Applications in the period 1965 to 1970, a number of which have already been approved (RX 394-95, 407-08, 2290-91). The purpose for Warner-Lambert's applications was to include single-ingredient antihistamines in a so-called "pull-back" system of dispensing drugs in hospitals and extended care facilities. The record does not show whether this new package has been approved but in any event hospital sales of single-ingredient antihistamines in 1970 accounted for only 7.8 percent of total sales. Consequently, even if Warner-Lambert were eliminated as a potential entrant, it would be *de minimis* (Tr. 3473-74; RX 2423).

67. In view of the fact that Warner-Lambert had dropped out of the single-ingredient market prior to the merger and the lack of any

substantial evidence that it was a potential entrant and the existence of a large number of firms in this market (43 in 1971), many of them among the largest ethical drug houses (RX 1695-99), the record will not support a finding that the acquisition of Parke, Davis will have the effect of substantially lessening competition in the single-ingredient antihistamine market.

[32] 68. *Irritant Laxatives (Ethical)*. Laxatives are products which stimulate or ease defecation (Tr. 804, 3360). They are generally self-prescribed (Tr. 3635, 3359-60) and can be purchased without a prescription (Tr. 817-18). The physician's usual role is to discourage laxative usage (Tr. 949-50), except in the case of hospitalized patients or out-patients with specific therapeutic problems (Tr. 804-05, 3635). A number of laxatives are promoted directly to the public through the media, while others are ethically promoted (CX 2031-37; Tr. 3637). Regardless of the method of promotion, all laxatives are shelved together in retail outlets (Tr. 3636-37).

69. Laxatives contain ingredients which are pharmacologically classified as irritants, salines, bulk formers, oils and emollients, and stool softeners (Tr. 807-09, 3012, 3359-61). With the exception of simple lubricants, all essentially act in the same way: "More material comes down to fill the rectum and it stimulates evacuation." (Tr. 3361) A number of laxatives combine ingredients from the different pharmacologic categories (RX 1745, n. 2). Warner-Lambert and Parke, Davis both market laxatives (RX 1726).

70. Counsel in support of the complaint allege that irritant laxatives promoted ethically constitute a relevant product submarket. They further contend that within this alleged submarket, the merger has eliminated substantial existing competition. Respondent contends that complaint counsel's submarket definition excludes many therapeutically and economically interchangeable products; that there is no basis in the record for classifying Warner-Lambert's combination product, Agoral, as an irritant; and that even assuming counsel in support of the complaint were otherwise correct, the merger still would have no substantial anticompetitive effect.

71. Neither the industry nor the public recognize irritant laxatives as distinct from others. All of the evidence establishes that the layman is not aware of the pharmacologic distinctions among laxative ingredients and so cannot distinguish so-called irritants from others (Tr. 950, 3636). The package inserts do not provide this information (Tr. 3637); in fact, the terms "irritant," [33] "irritant ingredient," or "irritant laxative" do not appear in any of the package inserts for laxatives which contain irritant ingredients. In every case the product is described simply as a "laxative" (CX 3163-68, 3171, 3173, 1991-93) or

“cathartic” (CX 3169-70). Moreover, nowhere in Parke, Davis’ marketing documents do the terms “irritant,” “irritant ingredient,” or “irritant laxative” appear (CX 2002-07).

72. While there are classifications for various laxative ingredients based on method of action, these classifications do not establish any economically significant peculiar characteristics or uses. They all ultimately act in the same way (Tr. 804, 3360-61). It is of interest to note that counsel in support of the complaint single out irritant laxatives (ethical) from all of the other various types of laxatives in this instance, while in other submarkets, such as the antianginal drugs, they make the claim that all the products are competitive since they are all ultimately designed to relieve the pain of an anginal attack despite the fact that Parke, Davis’ nitroglycerin works in a substantially different fashion than Warner-Lambert’s nitrates. This is likewise true of the approach of counsel in support of the complaint in the thyroid preparations market.

Consequently, it is concluded that irritant laxatives (ethical) is not a realistic submarket within which to attempt to judge this merger.

73. In any event, even if the irritant laxatives (ethical) is a proper submarket, the record would not support a market of substantially lessening competition. According to the evidence relied upon by counsel in support of the complaint, Warner-Lambert in 1969 was ranked eighth in the industry with a 2.8 percent market share, and Parke, Davis was seventh with a 3.7 percent market share. The combined share would have given the merged firm a rank of sixth, an advance of only one position over Parke, Davis’ pre-merger rank (CX 2042). Moreover, Parke, Davis’ 1969 irritant laxative sales were primarily due to one product, Alophen, with sales of \$932,000 (CX 2021). [34] This product was described by counsel in support of the complaint’s expert witness as an obsolete product (Tr. 954-56, 1393-94; CX 2002, 2004). Warner-Lambert’s product Agoral was a combination product of irritant and emollient ingredients and did not have the principal characteristics attributed to irritant laxatives (Tr. 809-10, 951-54). It is found that competition from other laxatives must be considered and this substantially reduces the position of Parke, Davis and Warner-Lambert in the industry with neither of them among the top 12 firms (RX 1726). Laxative products are relatively easy to formulate and many companies, large and small, are active in all segments of the laxative field. In 1969, DKK reported sales by a total of 74 manufacturers in the ethical irritant category (CX 2021-30). In 1969, DKK reported sales by 175 laxative manufacturers, 125 of which were promoting ethical laxatives.

74. It is concluded, therefore, that the record will not support a

finding of substantial lessening of competition in the irritant laxative (ethical) or any other laxative market as a result of the merger.

75. *Prenatal Vitamins*. Prenatal vitamins are vitamins formulated to meet the requirements of pregnant women, who require the same vitamins as other adults but in different quantities, therefore calling for a somewhat different formulation. Prenatal vitamins are an ethical submarket since the products are promoted to obstetricians who recommend them to their patients (Tr. 824-27, 3420). Parke, Davis is an existing and leading competitor in the prenatal vitamins market accounting for 14.9 percent of the total market in 1969 (CX 2349). Its sales in 1969 were \$2,170,000 and in 1970, \$2,300,000.

76. Warner-Lambert no longer makes prenatal vitamins. Its product was introduced in 1953 and only promoted until about 1960 because of its lack of marketing success. DKK figures show that sales of Warner-Lambert's prenatal vitamins declined from \$378,000 in 1958 to \$54,000 in 1967 and \$44,000 in 1971 (CX 2342; RX 1708; Tr. 3421). Warner-Lambert sales in 1969 and 1970 were \$46,000, accounting for 0.3 percent of the market in both these years.

[35] 77. Counsel in support of the complaint urge that Warner-Lambert was capable of reformulating its prenatal vitamin from a six-tablet a day requirement to a once-a-day preparation and consequently Warner-Lambert not only was eliminated as an existing competitor by the acquisition but also was a strong potential competitor in this market. There is little in the record to support this argument since the market was not one of consistent and substantial growth and had little attraction to any firm not well established. This is indicated by the fact that in addition to Warner-Lambert, nine other companies left this market between 1958 and 1971 (Tr. 3488-89; RX 1705, 1708). There are no high barriers to entry into this market other than getting your product recognized and prescribed by physicians. Prenatal vitamins are not novel or different from other types of vitamins of which there are more than 250 manufacturers (RX 1704-07).

78. The record will not support a finding that the merger here involved will tend to substantially lessen competition in the prenatal vitamins market.

79. *Antibiotics Useful Against Gram-Negative Bacilli*. Gram-negative bacilli are distinguished from other infecting organisms by a combination of two characteristics: their rod-like shape and the pink color they stain in a common diagnostic test (Tr. 1232-34, 2927-28). Gram-negative bacilli include numerous organisms, and the infections they cause may be treated either by antibiotics or by chemotherapeutic agents, such as sulfonamides (Tr. 3253-56; RX 2264; Tr. 2934-37, 2989-90, 1282-83, 1285, 1307, 1310, 1316). Antibiotics and other

antimicrobial agents active against gram-negative bacilli are not active against all gram-negative bacilli and are not effective exclusively against such bacilli but may destroy gram-negative cocci and gram-positive bacilli as well (RX 1, pp. 11-12; Tr. 1310). Antibiotics active against both gram-positive and gram-negative organisms are called "broad spectrum antibiotics." (CX 2454) Ampicillin, tetracycline, chloramphenicol, the cephalosporins and kanamycin, among others, are considered to be broad spectrum antibiotics (Tr. 1279, 1310-11, 2929-31; RX 1, pp. 11-12).

[36] 80. About twenty different antibiotics and chemo-therapeutic agents are active against gram-negative bacilli (Tr. 3253-56; RX 2264; Tr. 2934-35, 2937). The correct drug for a specific gram-negative infection will not be just any one of the antibiotics active against one or more of the gram-negative bacilli; rather, selection of the proper antimicrobial agent requires consideration of many factors, including the seriousness of the patient's condition, his medical history, the site of the infection, previous drug therapy, and the likely etiological agent. Clinical impressions must be supplemented by culture and sensitivity tests in order that the appropriate medication may be chosen (Tr. 1276-78, 1337-39, 2938-39, 3256-67).

81. Warner-Lambert markets one antibiotic, Coly-Mycin (colistin or polymyxin E) in various formulations: Parenteral (*i.e.*, injectable), oral suspension, otic, and ophthalmic (CX 2539-47). Parke, Davis markets four antibiotics having some gram-negative activity: chloramphenicol, tetracycline, ampicillin, and paromomycin (CX 2400-01, 2405-06, 2436-37, 2443-48).

82. This is an extremely complicated market and much time was devoted to it during the course of trial. The medical evidence is clear that the antibiotics of Parke, Davis may have a theoretical overlap with Warner-Lambert's Coly-Mycin products in that some of Parke, Davis' products are useful against certain gram-negative infecting organisms against which Parke, Davis' polymyxins may also be useful. An authoritative document in the record, the Medical Letter, Handbook of Antimicrobial Therapy, demonstrates that the use of alternative drugs is not carried out in practice. This letter (RX 1) demonstrates that for "each pathological organism there is generally one drug or occasionally a combination of drugs, that is likely to be a better choice than other drugs or drug combination. When the patient does not respond to a first-choice drug or cannot tolerate it, there is usually a preferred order of choice among alternative drugs." (RX 1, p. 8) The medical witnesses who testified agreed that this was the fact (Tr. 1275-77, 3260, 3268, 2939, 1328-29, 1333-35). In setting forth the drug of first-choice and alternatives for the various infecting

organisms of gram-negative nature, nowhere is it shown that Parke, Davis or a Warner-Lambert drug was the drug of first-choice and any other drug of either of the two [37] companies was recommended as the drug of second, third or fourth choice. In three instances drugs of Warner-Lambert or Parke, Davis are listed as alternative drugs for the same infection, however, in each of these three instances the first of the two companies drugs was listed as the third, fourth or fifth in the order of preference. It therefore appears that the actual competition which existed at the time of the merger was at best minimal.

83. In any event, even if counsel in support of the complaint's submarket definition were adopted, the merger could have no adverse effect on competition. Parke, Davis ranked seventh in 1970 with a 5.3 percent market share of this market and Warner-Lambert ranked twelfth with an 0.6 percent market share. Both companies had significant sales losses in 1971.

84. There is no evidence that Warner-Lambert's share of the market could possibly expand. Its Coly-Mycin sales were declining and were in danger of being replaced by a new antibiotic awaiting FDA approval (Tr. 2935-36, 3255, 3423-24, 3496, 1316-17, 2949-52). Moreover, in 1970, DKK reported 11 companies with a share greater than one percent and there were also 14 companies beside Warner-Lambert with shares of less than one percent who were important drug manufacturers (RX 1687-93).

85. The record will not support a finding that the merger of Parke, Davis and Warner-Lambert will tend to substantially lessen competition in the antibiotics useful against gram-negative bacilli market as contended by counsel in support of the complaint.

86. *Ampicillin*. Ampicillin, a broad spectrum, semi-synthetic penicillin, was patented by Beecham, and is sold in the United States by Beecham and licensed by Beecham to Bristol Laboratories, Inc. and Bristol-Myers Co. (CX 2520). Bristol has, in turn, sublicensed Squibb-Beechnut and American Home Products' Wyeth Division. In addition to Parke, Davis, which purchases ampicillin from Bristol in finished dosage form, Ayerst Laboratories Division of American Home Products and Lederle distribute ampicillin which they purchase in dosage form from Beecham (CX 2520). [38] A number of other companies also sell ampicillin (CX 2364; RX 1683-84), apparently without license. The record reveals that the ampicillin patent has been attacked successfully and other manufacturers can now come in with impunity (Tr. 1739). Warner-Lambert has never marketed ampicillin. Respondent has admitted that ampicillin is a relevant product submarket but disputes counsel in support of the complaint's conten-

tion that Warner-Lambert was a legally or competitively significant potential entrant into the ampicillin submarket.

87. Counsel in support of the complaint urge that Warner-Lambert was a potential entrant into the ampicillin submarket and that it was eliminated as a potential entrant as a result of its acquisition of Parke, Davis. The sole basis for this argument is that in 1968, Warner-Lambert approached Beecham to explore the possibility of obtaining licensing or marketing rights to one or more of Beecham antibiotics. After some discussions the matter was dropped. Beecham was not interested in the joint venture and Warner-Lambert had decided that ampicillin had become a generic product and not a specialty product of the type which Warner-Lambert marketed. In addition, there were a number of competitors in the ampicillin market making this a particularly unattractive market to Warner-Lambert. As a result Warner-Lambert discontinued any efforts to enter the ampicillin submarket well in advance of the merger (CX 2475-77, 2104, 2483-84; RX 760, 537; Tr. 3430-34). Consequently, there is no basis in the record for a finding that Warner-Lambert was eliminated as a potential entrant into the ampicillin submarket as a result of the merger and no finding of a tendency to substantially lessen competition in this market is warranted.

88. *Anti-Pseudomonas Drugs.* *Pseudomonas aeruginosa* is a species of gram-negative bacteria (Tr. 1235, 2489) which can cause relatively minor infections, such as swimmer's ear (Tr. 3422) or urinary tract infections (Tr. 3249), and also life-threatening infections in a compromised host, such as the severely burned or leukemic patient (Tr. 2489, 1293). There are presently four approved antibiotics active against *Pseudomonas*: gentamicin, carbenicillin, colistin (Warner-Lambert's Coly-Mycin) and polymyxin B (Tr. 2525, 1298). Warner-Lambert's largest selling Coly-Mycin product is its otic preparation used for ear infections, such as "swimmer's ear" (Tr. 3424, 3248). Parke, Davis' [39] only "anti-*Pseudomonas*" product is a Chloromycetin ophthalmic preparation to which polymyxin B has been added in order to reach *Pseudomonas* infections of the eye (CX 2559-60).

89. Counsel in support of the complaint contend that all drugs (including biologicals) active against *Pseudomonas* constitute the relevant product submarket. At present such drugs are limited to antibiotics and chemotherapeutic agents. They are included by counsel within the alleged submarket whether formulated in injectable, oral or topical form. Counsel in support of the complaint claim the merger has eliminated potential competition in this submarket because Parke, Davis is in the process of developing an anti-*Pseudomonas* vaccine for use in severely burned and cancer patients. Respondent disputes



complaint counsel's submarket definition, and further contends that Parke, Davis was not a significant potential entrant, and, even if it were, the merger can have no substantial adverse effect on competition in the so-called anti-Pseudomonas drugs submarket.

90. The products manufactured by Warner-Lambert and Parke, Davis are quite obviously altogether for different therapeutic applications and there is no evidence in the record that the industry, DKK or the FDA or anyone else has ever recognized this group of drugs as a separate economic entity. In any event, accepting this as a proper submarket, Warner-Lambert's share of the anti-Pseudomonas market in 1970 was 9.4 percent (down from 16.9 percent in 1969) and Parke, Davis' share was 0.5 percent in 1970 (CX 2535). By 1971 Warner-Lambert's share fell to 6.1 percent (RX 1776) since its products now competed against two new antibiotics active against Pseudomonas, including gentamicin. The insignificance of Parke, Davis' share of this market makes it evident that the merger would have no tendency toward anticompetitive effects.

91. Counsel in support of the complaint urge that Parke, Davis had filed an application for a new drug which would be used as a vaccine for use in burn patients filed with the Division of Biologics Standards on June 29, 1970 (Tr. 2473, 2586). At the time of the hearings, this application was still on file and it appeared dubious as to whether or not the application would ever be granted (Tr. 2604). This original application was limited to [40] claimed usefulness of the vaccine to burn injured patients. A new claim will be made that the drug is efficacious for leukemia patients as well (Tr. 2479, 2537-38, 2554). The expert witness had serious reservations as to this vaccine's usefulness because of its marginal and transient protection and severe side effects (Tr. 2953-55, 2956-57, 1297, 1355-56, 3271). Moreover, even if the application is approved by the Bureau of Biologics (successor to the Division of Biologics Standards), there would be no measurable effect on antibiotics usage or the use of Warner-Lambert's antibiotics since each product is designed for a specific purpose and would not result in the elimination of any of the products.

92. The record will not support a finding that the merger will tend toward any substantial lessening of competition in the anti-Pseudomonas drugs submarket.

93. *Normal Serum Albumin, Immune Serum Globulin, Tetanus Immune Globulin.* Normal serum albumin, immune serum globulin and tetanus immune globulin are each admitted to be relevant product submarkets. Parke, Davis produces and sells each of these products as generic, commodity products to hospitals and emergency rooms. Warner-Lambert does not produce or sell these or any other blood

fractions. Counsel in support of the complaint acknowledge that therapeutic blood fractionation is a very elaborate process requiring unique facilities, a qualified staff and a Federal license. Although Warner-Lambert possessed none of these prerequisites, counsel in support of the complaint nevertheless, rest their case on the claim that Warner-Lambert was an imminent and desirable entrant. The evidence establishes, however, that Warner-Lambert was not perceived as a potential entrant (Tr. 3001-02); that it never considered producing therapeutic blood fractions (Tr. 3435-36, 3439, 3374-76); that it had neither relevant experience capability nor incentive to become a significant entrant into this field (Tr. 3845-48, 3548, 3552-54, 3561-62; CX 1(T)-(Y)).

94. The fact that Warner-Lambert's General Diagnostics Division produces certain diagnostic blood products that are used as controls in hospitals and clinical laboratories does not make it a potential entrant into any of the blood fraction markets here involved (Tr. 3552-54, 3561-62).

[41] 95. Elizabeth Biochemicals, which was acquired by Warner-Lambert in 1969 (CX 2841), has conducted a clinical laboratory and operated blood donation centers (CX 2844). It currently has only one blood center which collects plasma from immunized donors for one of the products involved in this case, tetanus immune globulin. It does not, however, have a license to manufacture this product (Tr. 3562-63). Warner-Lambert's ownership of Elizabeth Biochemicals did not make it a likely potential into human blood fractionating since an owned blood supply has not proved to be advantageous to blood fractionators (Tr. 3549, 3551, 3555). Parke, Davis has never owned any of its blood supply. Moreover, half of Parke, Davis' raw material supply is secured not from blood centers but from placenta purchased from hospital delivery rooms (Tr. 3550-51). Two fractionators who presently own blood banks, Squibb and Merck, are trying to dispose of them (Tr. 3551, 3556).

96. Counsel in support of the complaint urge that Warner-Lambert was a substantial potential entrant into the blood fractionating business since it held a meeting with Squibb in 1969 to ascertain whether Squibb would be interested in a joint R&D program directed at developing blood specialty products which Squibb would manufacture for Warner-Lambert's distribution (CX 2886-87; Tr. 3462). This could well have resulted in Warner-Lambert selling some of the products here involved. It is clear, however, that Warner-Lambert was interested not so much in the blood fractionating business but was interested in developing some joint R&D program directed at future new products. This single meeting with Squibb did not make Warner-

Lambert a likely significant potential entrant into the blood fractionating business (CX 2886-87, 2891; Tr. 3462, 3511-12).

97. Officials of Warner-Lambert had a single meeting with the president of Cutter Laboratories in April of 1969 to discuss in a very preliminary manner whether or not Cutter would be interested in selling out to Warner-Lambert (Tr. 2995-3010). While Cutter is engaged in the blood fractionating business, this single breakfast meeting cannot be construed to mean that Warner-Lambert was interested in entering the blood fraction business.

[42] 98. The record will not support a finding that Warner-Lambert was a potential entrant into the three submarkets here involved or that the acquisition of Parke, Davis may be to substantially lessen competition in these submarkets.

#### CONCLUSIONS

1. The Federal Trade Commission has jurisdiction over the parties and the subject matter involved in this proceeding.

2. The entire United States is the appropriate geographic market, or "section of the country," within which to consider the effect on competition of the merger between Warner-Lambert and Parke, Davis & Company, a corporation, in this case.

3. The drug manufacturing industry and the ethical drug segment of that industry are each appropriate lines of commerce within which to consider the alleged anticompetitive effect of the merger between Warner-Lambert Company and Parke, Davis & Company.

4. It is concluded that the record does not demonstrate that the challenged merger may be substantially to lessen competition or to tend to create a monopoly in the drug manufacturing industry or the ethical drug segment of that industry, and the merger, therefore, does not violate Section 7 of the Clayton Act with respect thereto.

5. The following constitute appropriate lines of commerce within which to consider the alleged anticompetitive effects of the challenged merger:

(1) oral decongestants (2) cough drops and lozenges (3) cold remedies (4) antihistamines (5) antacids (6) emollient/protective dermatological preparations promoted ethically (7) prenatal vitamins (8) ampicillin (9) urinary antibacterials (non-sulfa) [43] (10) mouthwash (11) normal human serum albumin (12) immune serum globulin (13) tetanus immune globulin

6. It is concluded that the merger is not likely to substantially lessen competition or tend to create a monopoly in any of the foregoing lines of commerce, and the merger, therefore, does not violate Section 7 of the Clayton Act with respect thereto.

7. It is concluded that the following alleged product submarkets are not appropriate lines of commerce for Section 7 purposes:

(1) thyroid preparations (2) anti-anginal drugs (3) cough remedies (4) bronchial dilators (5) irritant laxatives (ethical) (6) antibiotics useful against gram-negative bacilli (7) anti-pseudomonas drugs

8. It is concluded, however, that even if any of the above alleged product submarkets were a proper line of commerce for Section 7 purposes, it is not likely that the merger may be substantially to lessen competition or to tend to create a monopoly in any of said alleged submarkets, and, therefore, the merger would not violate Section 7 of the Clayton Act therein.

ORDER

*It is ordered,* That the complaint in this matter be, and it hereby is, dismissed.

Initial Decision

87 F.T.C.

APPENDIX A, p. 1

DRUG ETHICAL MARKET

RX 1862 Revised A

- MANUFACTURER -	TOP 30 FIRMS														
	RANKS 1957 - 1971														
	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967	1968	1969	1970	1971
LILLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
AMERICAN CYANAMID	2	5	6	6	5	5	6	7	7	11	11	11	12	13	15
AMERICAN HOME PRODUCTS	3	3	3	5	2	3	3	2	2	3	2	2	3	3	3
UPJOHN	4	2	2	2	4	4	4	4	5	6	7	7	7	11	10
PARKE, DAVIS	5	6	6	3	7	7	8	10	10	10	12	12	11	Merged into W-L	
SMITH, KLINE & FRENCH	6	4	4	4	3	2	2	3	3	5	5	6	8	8	12
BEECHNUT	7	8	8	8	8	8	10	9	9	8	9	9	9	9	10
ABBOTT	8	9	9	9	9	10	9	8	8	7	8	8	6	7	8
PFIZER	9	10	10	10	10	11	11	11	11	9	10	10	10	12	11
SCHERING	10	11	11	11	14	15	16	17	17	19	18	15	14	14	13
MERCK & CO.	11	7	7	7	6	6	5	5	4	2	3	3	4	4	4
CIBA <sup>1</sup>	12	13	13	14	13	12	13	15	15	16	17	19	20	9	7
STERLING	13	12	12	12	15	14	15	14	14	14	15	18	17	17	19
MEAD JOHNSON	14	14	14	15	12	17	17	18	18	18	Merged into Bristol-Myers				
WARNER-LAMBERT	15	15	15	16	16	13	12	13	13	12	14	14	16	5	5
SEARLE	16	16	18	19	18	16	14	12	12	13	13	13	13	16	16
ROCHE	17	18	18	13	11	9	7	6	6	4	4	4	2	2	2
RICHARDSON-MERRELL <sup>2</sup>	18	17	17	17	17	19	22	21	22	24	23	23	23	21	21
BURROUGHS WELLCOME	19	20	20	20	22	22	21	23	23	23	22	22	22	20	20
ROBINS	20	19	19	18	19	18	18	16	16	17	16	17	18	18	17
CARTER-WALLACE	21	21	21	21	20	21	20	22	25	25	24	25	25	28	30
MCMILL	22	23	Merged into Johnson & Johnson												
ATLAS CHEMICAL	23	27	*	*	*	*	30 <sup>3</sup>	30 <sup>3</sup>	30 <sup>3</sup>	34	32	23	29	29	29
UNITED STATES VITAMIN	24	25	26	28	29	27	26	29	30	29	29	30	27	25	25
GEIGY	25	22	23	23	21	20	19	19	19	21	20	21	21	Merged w/Ciba	
SANDOZ	26	28	28	26	26	25	24	25	24	22	21	20	19	19	18
NORWICH <sup>3</sup>	27	24	24	25	27	28	27	27	27	26	25	26	25	24	24
JOHNSON & JOHNSON	28	29	22	22	23	23	23	20	20	20	19	16	16	15	14
DOW	29	*	*	*	*	*	34	33	31	32	31	31	30	34	*
LAKESIDE	30	*	*	*	*	*	*	*	*	*	*	*	*	*	*
SMITH DORSEY	*	26	27	27	28	*	32	34	35	35	38	37	Merged w/Sandoz		
BRISTOL-MYERS	*	30	25	24	24	24	25	24	21	18	15	6	5	5	6
WALLACE & TIERNAN	*	*	29	29	30	*	35	35	34	36	37	40	38	35	*
ENDO*	*	*	30	30	*	30	30	32	32	33	35	34	34	30	31
BEKALL	*	*	*	25	26	28	25	26	26	26	27	26	27	31	*
RORER	*	*	*	*	29	29	29	28	28	28	27	24	24	22	23
MILES	*	*	*	*	30	30	30	29	30	30	30	30	30	32	*
BAXTER	*	*	*	*	*	30	31	31	31	31	28	27	28	23	22
MARION	*	*	*	*	*	31	31	31	31	31	31	31	30	27	27
HOECHST	*	*	*	*	*	31	31	31	31	31	31	31	31	26	24
AMERICAN HOSPITAL SUPPLY	*	*	*	*	*	31	31	31	31	31	31	31	31	31	28

<sup>1</sup> Known as Ciba-Geigy since 1970.  
<sup>2</sup> Known as Vick in 1957 and 1958.  
<sup>3</sup> Known as Morton-Norwich since 1969.  
 \* Known as Du Pont since 1969.  
 \* Indicates firm was not in top 30 firms.

Handwritten numbers indicate rank according to FTC Exhibits 3365-69.  
 \*Handwritten \* implies below 50.

21 November 1973

Source: RX 1800-1829.

APPENDIX A, p. 2

RX 1863 Revised

MANUFACTURER -	D&K ETHICAL MARKET															
	TOP 30 FIRMS															
	MARKET SHARES 1957 - 1971															
	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967	1968	1969	1970	1971	
LILLY	8.54	7.99	7.54	7.04	7.39	7.20	6.89	6.61	6.57	6.78	7.06	7.28	7.37	7.50	7.64	
AMERICAN CYANAMID	6.99	6.10	5.85	5.91	5.51	5.27	5.09	4.33	4.34	3.69	3.30	3.09	2.89	2.71	2.54	
AMERICAN HOME PRODUCTS	6.88	6.84	6.56	5.98	6.28	6.10	5.94	6.15	5.82	6.10	6.32	6.23	6.31	6.20	6.20	
UPJOHN	6.66	6.80	6.74	6.45	6.14	5.78	5.60	5.22	5.24	4.94	4.63	4.38	4.17	3.75	3.62	
FARLE, DAVIS	5.96	6.09	5.84	6.02	4.86	4.55	4.27	4.15	4.04	3.70	3.26	2.93	2.90	Merged into W-L		
SMITH, KLINE & FRENCH	5.74	6.11	6.11	6.01	6.19	6.27	6.23	5.83	5.62	5.22	5.04	4.50	4.17	3.87	3.49	
BEECHMUT	4.94	4.52	4.38	4.38	4.19	4.11	4.03	4.17	4.11	4.02	3.73	3.56	3.66	3.74	3.79	
ABBOTT	4.60	4.48	4.31	4.07	3.87	3.93	4.12	4.19	4.18	4.22	4.07	4.35	4.47	4.51	3.83	
PFIZER	3.87	3.70	3.51	3.37	3.53	3.65	3.99	3.98	3.80	3.95	3.69	3.33	3.32	3.57	3.55	
SCHERING	3.71	3.23	2.94	3.00	2.62	2.38	2.12	2.04	1.99	2.05	2.03	2.22	2.36	2.49	2.65	
MERCK & CO.	3.54	4.64	5.17	5.07	5.23	4.86	5.19	5.18	5.38	6.21	6.14	5.97	5.90	5.80	5.82	
CIBA <sup>1</sup>	2.54	2.54	2.57	2.47	2.64	2.59	2.62	2.44	2.28	2.18	2.06	2.02	1.99	3.83	3.95	
STERLING	2.44	2.59	2.62	2.50	2.45	2.39	2.29	2.50	2.40	2.29	2.24	2.03	2.25	2.12	2.00	
MEAD JOHNSON	2.34	2.22	2.21	2.30	3.02	2.14	2.00	1.84	1.86	2.06	Merged into Bristol-Myers					
WARNER-LAMBERT	1.77	1.91	1.87	2.00	2.27	2.54	2.70	2.53	2.54	2.60	2.43	2.41	2.31	5.05	4.81	
SEARLE	1.66	1.65	1.61	1.63	1.85	2.22	2.40	2.89	2.66	2.59	2.73	2.66	2.50	2.39	2.48	
ROCHE	1.64	1.53	1.66	2.48	3.37	4.02	4.33	4.83	5.18	5.26	5.70	5.96	6.52	6.71	6.90	
RICHARDSON-MERRELL <sup>2</sup>	1.36	1.54	1.62	1.71	1.87	1.62	1.35	1.44	1.34	1.33	1.35	1.26	1.23	1.24	1.25	
BURROUGHS WELLCOME	1.35	1.36	1.39	1.38	1.42	1.39	1.36	1.31	1.33	1.36	1.42	1.44	1.49	1.55	1.64	
ROBINS	1.28	1.39	1.55	1.70	1.79	1.94	1.96	2.05	2.11	2.06	2.07	2.13	2.10	2.11	2.09	
CARTER-MALLACE	0.89	1.03	1.28	1.38	1.49	1.50	1.49	1.37	1.27	1.06	0.96	0.92	0.83	0.76	0.67	
MCNEIL	0.61	0.66	Merged into Johnson & Johnson													
ATLAS CHEMICAL	0.57	0.54	*	*	*	*	*	*	*	*	*	*	0.74	0.76	0.75	0.77
UNITED STATES VITAMIN	0.53	0.59	0.61	0.62	0.63	0.76	0.74	0.67	0.63	0.62	0.65	0.72	0.81	0.93	0.99	
GEIGY	0.52	0.77	1.09	1.26	1.47	1.58	1.62	1.79	1.80	1.67	1.77	1.71	1.74	Merged w/Ciba		
SANDOZ	0.50	0.51	0.56	0.68	0.81	0.99	1.10	1.18	1.29	1.36	1.44	1.94	2.03	2.07	2.03	
NORWICH <sup>3</sup>	0.50	0.62	0.70	0.71	0.73	0.73	0.74	0.78	0.79	0.84	0.86	0.89	0.91	0.94	0.93	
JOHNSON & JOHNSON	0.49	0.50	1.28	1.28	1.33	1.33	1.32	1.63	1.74	1.76	2.03	2.17	2.30	2.41	2.56	
DOW	0.42	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
LAKESIDE	0.41	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
SMITH DORSEY	*	0.56	0.57	0.64	0.64	*	*	*	*	*	*	*	*	Merged w/Sandoz		
BRISTOL-MYERS	*	0.50	0.61	0.75	0.98	1.08	1.08	1.26	1.66	2.27	4.68	5.08	5.10	4.71	4.66	
WALLACE & TIERNAN	*	*	0.54	0.59	0.61	*	*	*	*	*	*	*	*	*	*	
ENDO <sup>4</sup>	*	*	0.52	0.57	*	0.62	*	*	*	*	*	*	*	0.61	*	
REKALL	*	*	*	*	0.82	0.77	0.73	0.78	0.81	0.79	0.74	0.72	*	*	*	
RORER	*	*	*	*	*	0.68	0.69	0.71	0.71	0.69	0.73	1.04	0.97	0.97	1.07	
NILES	*	*	*	*	*	0.62	*	0.64	0.64	0.62	0.60	*	*	*	*	
BAXTER	*	*	*	*	*	*	*	*	*	*	0.65	0.78	0.81	0.96	1.25	
MARION	*	*	*	*	*	*	*	*	*	*	*	*	0.76	0.77	0.82	
HOECHST	*	*	*	*	*	*	*	*	*	*	*	*	*	0.83	1.00	
AMERICAN HOSPITAL SUPPLY	*	*	*	*	*	*	*	*	*	*	*	*	*	*	0.81	

<sup>1</sup> Known as Ciba-Geigy since 1970.  
<sup>2</sup> Known as Wyeth from 1947 and 1958.  
<sup>3</sup> Known as Norwich-Knowlton since 1969.  
<sup>4</sup> Indicated firm was not in top 30 firms.  
 \* November 1971  
 \* Purchased RX 1800-1829.

Initial Decision

87 F.T.C.

DKK ETHICAL & PROPRIETARY MARKET

Re 1863 Revised.

APPENDIX A, p. 3

TOP 30 FIRMS

- MANUFACTURED -	RANKS 1957 - 1971										1969	1970	1971		
	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966				1967	1968
LILLY	1	2	2	2	2	2	3	2	2	2	2	2	2	2	2
AMERICAN HOME PRODUCTS	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
AMERICAN CYANAMID	3	4	5	6	5	5	6	9	7	11	13	13	16	17	17
UPJOHN	4	3	3	3	4	4	4	4	5	6	7	7	9	13	13
PARKE, DAVIS	5	6	6	4	7	7	8	10	11	10	12	14	15	Merged into	
SMITH, KLINE & FRENCH	6	5	4	5	3	3	2	3	3	4	6	6	6	8	10
BEECHNUT	7	8	8	8	8	8	10	7	9	9	10	11	11	12	12
ABBOTT	8	9	9	10	9	9	9	8	8	8	8	8	7	7	11
Pfizer	9	10	10	12	11	11	11	11	10	7	9	10	10	9	7
SCHERING	10	12	12	13	15	16	16	17	18	18	19	18	17	14	15
STERLING	11	11	11	11	12	12	12	12	12	14	11	9	8	10	8
MERCK & CO.	12	7	7	7	6	6	5	5	4	3	3	4	5	6	6
WARNER-LAMBERT	13	13	13	14	16	13	13	13	13	12	14	12	12	4	4
CIBA <sup>1</sup>	14	14	14	17	17	16	14	15	16	17	20	20	20	11	9
MEAD JOHNSON	15	16	16	9	10	17	18	21	21	21	Merged into Bristol-Myers				
RICHARDSON-MERRELL <sup>2</sup>	16	15	15	15	14	14	17	16	17	16	17	16	14	16	16
SEARLE	17	17	19	20	19	18	15	14	14	15	15	17	18	18	18
ROCHE	18	18	18	16	13	10	7	6	6	5	4	5	3	3	3
BURROUGHS WELLCOME	19	21	24	24	26	25	24	24	23	23	23	24	24	22	21
BRISTOL-MYERS	20	19	22	21	20	19	20	18	15	13	5	3	4	5	8
ROBINS	21	20	20	19	21	20	19	19	19	20	18	19	19	19	19
MILES	22	27	23	23	25	26	26	26	26	25	24	23	23	21	22
J B WILLIAMS	23	26	29	*	29	*	28	33	33	34	32	29	30	32	*
CARTER-MALLACE	24	22	21	22	22	22	23	23	24	28	27	*	*	30	*
NORMICH <sup>3</sup>	25	24	25	27	27	27	28	28	28	27	25	25	25	23	23
MCKESSON ROBBINS	26	25	28	28	*	*	31	31	30	30	31	32	31	36	*
JOHNSON & JOHNSON	27	28	17	18	18	21	21	20	20	19	16	15	13	15	14
REXALL	28	23	26	25	23	24	25	25	27	26	26	26	28	44	*
MCNEIL	29	30	Merged into Johnson & Johnson												1
ATLAS CHEMICAL	30	*	*	*	*	*	38	39	39	35	36	34	35	31	30
GEIGY	*	29	27	26	24	23	23	22	22	22	21	22	22	Merged w/Ciba	
WALLACE & TIERNAN	*	*	30	30	30	30	29	29	29	30	30	33	34	33	*
SANDOZ	*	*	*	29	28	28	27	27	25	24	22	23	24	20	20
UNITED STATES VITAMIN	*	*	*	*	*	29	30	30	30	29	28	28	26	24	26
RORER	*	*	*	*	*	*	32	30	31	29	28	27	27	25	25
BLOCK DRUG	*	*	*	*	*	*	30	30	30	30	31	30	29	27	28
BAXTER	*	*	*	*	*	*	40	34	37	37	33	32	32	26	27
HOECHST	*	*	*	*	*	*	3	3	3	3	4	3	3	28	28
MARION	*	*	*	*	*	*	4	4	4	4	4	4	3	29	29
AMERICAN HOSPITAL SUPPLY	*	*	*	*	*	*	40	40	40	40	40	40	37	37	29

<sup>1</sup> Known as Ciba-Geigy since 1970.

<sup>2</sup> Known as Vick in 1957 and 1958.

<sup>3</sup> Known as Norton-Normich since 1969.

\* Indicates firm was not in top 30 firms.

Source: RI 1830-1859.

Handwritten numbers indicate rank according to PTC Exhibits 3360-3364  
 \*Handwritten \* implies below 50.

Initial Decision

APPENDIX A, p. 4

DKK ETHICAL & PROPRIETARY MARKET

RX 1865 Revised

MANUFACTURER -	TOP 30 FIRMS															
	MARKET SHARES 1957 - 1971															
	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967	1968	1969	1970	1971	
LILLY	7.38	6.86	6.46	5.94	6.21	6.11	5.88	5.70	5.67	5.82	6.06	5.83	5.97	6.16	6.30	
AMERICAN HOME PRODUCTS	7.02	7.36	7.29	6.77	6.79	6.53	6.28	6.51	6.11	6.33	6.52	6.58	6.63	6.56	6.53	
AMERICAN CYANAMID	6.07	5.30	5.05	5.02	4.66	4.47	4.33	3.73	3.74	3.17	2.83	2.47	2.34	2.23	2.11	
UPJOHN	5.75	5.91	5.77	5.45	5.17	5.11	4.99	4.66	4.66	4.35	4.06	3.60	3.48	3.16	3.05	
PARKE, DAVIS	5.15	5.23	5.01	5.08	4.17	3.96	3.74	3.67	3.57	3.25	2.87	2.43	2.42	Merged into W-L		
SMITH, KLINE & FRENCH	4.96	5.25	5.24	5.08	5.27	5.63	5.89	5.59	5.39	5.12	4.86	4.26	3.92	3.67	3.34	
BEECHMUT	4.27	3.88	3.76	3.69	3.71	3.70	3.68	3.80	3.74	3.59	3.32	3.08	3.17	3.24	3.25	
ABBOTT	3.98	3.85	3.70	3.43	3.50	3.56	3.70	3.76	3.74	3.73	3.60	3.59	3.76	3.80	3.25	
PFIZER	3.35	3.26	3.09	2.87	3.01	3.33	3.59	3.59	3.66	3.76	3.55	3.15	3.20	3.50	3.44	
SCHERING	3.21	2.92	2.66	2.66	2.38	2.20	1.98	1.95	1.90	1.95	1.92	1.97	2.09	2.64	2.80	
STERLING	3.15	3.05	3.05	2.97	2.93	2.90	2.83	2.95	2.95	2.24	3.02	3.54	3.60	3.45	3.41	
MERCK & CO.	3.06	3.99	4.43	4.28	4.45	4.26	4.58	4.62	4.79	5.47	5.40	4.94	4.95	4.99	4.96	
WARNER-LAMBERT	2.48	2.66	2.41	2.42	2.37	2.73	2.80	2.64	2.69	2.84	2.71	3.08	3.10	5.47	5.27	
CIBA <sup>1</sup>	2.20	2.18	2.21	2.09	2.22	2.20	2.23	2.11	2.05	1.97	1.88	1.76	1.75	3.28	3.38	
HEAD JOHNSON	2.03	1.91	1.89	3.45	3.33	2.12	1.85	1.67	1.67	1.82	Merged into Bristol-Myers					
RICHARDSON-MERRELL <sup>2</sup>	1.56	1.93	2.02	2.24	2.41	2.38	1.96	1.96	1.94	2.05	2.04	2.26	2.46	2.23	2.22	
SEARLE	1.43	1.42	1.38	1.38	1.56	1.88	2.21	2.48	2.30	2.22	2.34	2.12	2.02	1.96	2.04	
ROCHE	1.42	1.31	1.42	2.09	2.84	3.46	3.85	4.31	4.63	4.65	4.99	4.90	5.41	5.61	5.77	
BURROUGHS WELLCOME	1.17	1.17	1.19	1.17	1.20	1.18	1.16	1.14	1.16	1.17	1.22	1.15	1.21	1.28	1.36	
BRISTOL-MYERS	1.14	1.26	1.24	1.34	1.52	1.75	1.69	1.82	2.18	2.78	4.06	5.22	5.25	5.12	4.97	
ROBINS	1.11	1.19	1.33	1.44	1.51	1.65	1.72	1.82	1.89	1.83	1.93	1.89	1.88	1.88	1.86	
MILES	0.99	0.73	1.21	1.20	1.21	1.16	1.08	1.04	1.10	1.14	1.11	1.35	1.39	1.32	1.28	
J B WILLIAMS	0.92	0.86	0.68	*	0.62	*	*	*	*	*	*	0.78	0.73	*	*	
CARTER-WALLACE	0.92	1.03	1.25	1.29	1.37	1.37	1.36	1.26	1.15	0.94	0.85	*	*	0.66	*	
NORWICH <sup>3</sup>	0.90	0.93	0.98	0.98	0.95	0.92	0.89	0.96	0.94	0.98	1.01	1.09	1.08	1.11	1.09	
MCKESSON ROBBINS	0.77	0.86	0.78	0.71	*	*	*	*	*	0.61	*	*	*	*	*	
JOHNSON & JOHNSON	0.67	0.72	1.51	1.52	1.64	1.60	1.54	1.76	1.87	1.89	2.13	2.42	2.53	2.57	2.81	
REXALL	0.61	0.97	0.97	1.16	1.27	1.18	1.16	1.07	1.08	1.09	0.94	0.87	0.77	*	*	
MCNEIL	0.52	0.57	Merged into Johnson & Johnson													
ATLAS CHEMICAL	0.49	*	*	*	*	*	*	*	*	*	*	*	*	*	0.64	
SEIGY	*	0.66	0.94	1.06	1.23	1.34	1.38	1.54	1.55	1.43	1.51	1.37	1.41	Merged w/Ciba		
WALLACE & TIERNAN	*	*	0.54	0.56	0.60	0.64	0.69	0.66	0.66	*	0.60	*	*	*	*	
SANDOZ	*	*	*	0.57	0.68	0.84	0.94	1.02	1.11	1.16	1.23	1.55	1.64	1.70	1.67	
UNITED STATES VITAMIN	*	*	*	*	*	0.65	0.63	*	0.65	0.69	0.72	0.78	0.84	0.92	0.96	
RORER	*	*	*	*	*	*	*	0.61	*	*	0.63	0.83	0.79	0.79	0.88	
BLOCK DRUG	*	*	*	*	*	*	*	*	*	*	*	0.77	0.77	0.73	0.76	
BAXTER	*	*	*	*	*	*	*	*	*	*	*	*	*	0.79	1.02	
HOECHST	*	*	*	*	*	*	*	*	*	*	*	*	*	0.68	0.82	
MARION	*	*	*	*	*	*	*	*	*	*	*	*	*	0.68	*	
AMERICAN HOSPITAL SUPPLY	*	*	*	*	*	*	*	*	*	*	*	*	*	*	0.67	

<sup>1</sup> Known as Ciba-Geigy since 1970.

<sup>2</sup> Known as Vick in 1957 and 1958.

<sup>3</sup> Known as Morton-Norwich since 1969.

\* Indicates firm was not in top 30 firms.

Source: RX 1830-1859.



## OPINION OF THE COMMISSION

By NYE, *Commissioner*:

[1] This is an appeal by counsel supporting the complaint from a decision of the administrative law judge dismissing the complaint.<sup>1</sup> [2]

## PROCEEDINGS BELOW

The Commission issued a complaint against respondent Warner-Lambert Company (hereinafter referred to as "Warner-Lambert") on June 30, 1971, alleging that its acquisition of Parke, Davis & Company (hereinafter referred to as "Parke, Davis") on November 13, 1970, violated Section 7 of the Clayton Act, as amended (15 U.S.C. §18). The complaint alleged that the acquisition may have substantially lessened competition in the overall drug manufacturing market<sup>2</sup> in the ethical segment<sup>3</sup> thereof, and in many discrete therapeutic markets.<sup>4</sup> On August 2, 1974, after extensive hearings, [3] Administrative Law Judge Andrew C. Goodhope filed an initial decision concluding that the acquisition was not in violation of Section 7 of the Clayton Act. Accordingly, he dismissed the complaint.

## THE ACQUIRING COMPANY

Warner-Lambert manufactures and sells many products throughout the world, among them ethical and proprietary drugs. In 1969, the year prior to the acquisitions, Warner-Lambert had total sales of \$807.5

<sup>1</sup> For convenience, the following abbreviations are used in this opinion:

Comm. Find.—Commission Findings of Facts, cited by paragraph number. I.D.—Initial decision of administrative law judge (Findings cited by paragraph number; conclusions cited by page number). Tr.—Transcript of testimony CX—Commission exhibit RX—Respondent exhibit App. Br.—Brief on Appeal of complaint counsel Ans. Br.—Answering Brief of respondent Rep. Br.—Reply Brief of complaint counsel CPF—Complaint counsel's proposed findings ALJ—Administrative Law Judge.

<sup>2</sup> The "overall drug manufacturing market" consists of all medicines, both pharmaceutical and biological, in dosage form and restricted to those intended for human use. It includes all ethical and proprietary drugs.

<sup>3</sup> For purposes of this opinion, "ethical drugs" means those promoted to doctors. In most instances, the ultimate user may obtain an ethical drug only by doctor's prescription. Some ethical drugs may be purchased by the user without a prescription. But even they are ordinarily purchased on a doctor's recommendation. "Proprietary drugs" means those promoted through television and other media directly to the ultimate user and obtainable without a prescription. Proprietary drugs are not alleged to be a separate line of commerce relevant for consideration, other than as part of the overall drug market.

<sup>4</sup> The complaint alleged that 55 specified therapeutic markets "among others" were adversely affected by the Parke, Davis acquisition. By its Motion for Summary Decision, Appendix 1, March 15, 1972, complaint counsel conceded they expected to prove competitive injury in no more than 49 therapeutic markets. Thereafter, the number of contested markets dwindled to 45, of which 22 were included by complaint counsel "solely to show the breadth of competition between the merging parties in the Complaint's two major markets" (Complaint Counsel's Limitation of Proof, March 8, 1973). Subsequently, all proof with regard to those 22 markets was barred by ruling of the ALJ (Tr. 871, October 16, 1973). During the course of the hearing, complaint counsel abandoned three additional submarkets, two of which were dropped in response to a Commission order of October 5, 1973, barring evidence of "pre-NDA" (New Drug Application) research "on the question of whether a firm should be considered a potential entrant into a market because of research activity."

million, of which domestic drug sales accounted for slightly less than 18 percent.<sup>5</sup> These sales (\$143.5 million) represented some 3.1 percent of the overall domestic drug market and made Warner-Lambert the twelfth largest seller in the industry for that year. Warner-Lambert had domestic ethical drug sales of approximately \$87.3 million in 1969. It ranked fifteenth in ethical sales, with a 2.3 percent share of the market in that year. Most of these drug sales were made by Warner-Lambert's Warner-Chilcott division, the successor of a firm acquired by Warner-Lambert in 1952. Proprietary drug sales by Warner-Lambert amounted to \$56.2 million in 1969.

In 1970 Warner-Lambert spent some \$126 million for domestic advertising (television, newspapers, periodicals, etc.), making it the single largest drug and cosmetic advertiser in the country and the fifth largest among all advertisers. Warner-Lambert's promotional activities have helped place many of its products among the dominant sellers in their respective markets. Several of Warner-Lambert's brand names have literally become household words, such as Listerine, Bromo Seltzer, Anahist, Smith Brothers Cough Drops, and Roloids.

Although there is no evidence that Warner-Lambert's ethical drug management follows the lead of its consumer product management in promotional strategy, some similarity in the marketing efforts of the two is nonetheless apparent. Unlike many ethical drug sellers (including Parke, Davis), Warner-Lambert sells only trade-named ethical drugs. Such drugs are not sold on the basis of the generic, or underlying [4] chemical, names which competitors may also use. Instead, they are sold under unique trade names promoted through personal solicitation of doctors by trained "detail" representatives, direct mail contact and advertising in professional journals. Warner-Lambert's management refers to its branded ethical promotional strategy as a "specialty" approach (Tr. 3375, CX 1(T)).

#### THE ACQUIRED COMPANY

Parke, Davis is an old, well-established pharmaceutical products company. It operates throughout the world and produced total sales of \$273.5 million in 1969, of which domestic drug sales represented approximately 40 percent.<sup>6</sup> Parke, Davis has emphasized ethical pharmaceutical products and, as a result, its proprietary sales are minimal. In 1969 Parke, Davis' ethical drug sales of \$109.5 million

<sup>5</sup> Warner-Lambert's other activities include ophthalmic and scientific instruments, ophthalmic and dental supplies, safety products, chemicals, candy, confectionaries, cosmetics and toiletries. Warner-Lambert also has an international division whose sales comprise 23 percent of 1969 total sales.

<sup>6</sup> Besides its domestic drug sales, Parke, Davis sold medical instruments, hospital and physicians' supplies, athletic products, support hose, nutritional and veterinary products and chemicals. These accounted for approximately \$160 million in sales.

placed it in eleventh position among ethical drug sellers with a 2.9 percent market share (CX 873). Its proprietary drug sales amounted to \$3.4 million dollars. In overall drug sales, Parke, Davis' \$112.9 million in sales in 1969 constituted a 2.42 percent market share and ranked it fourteenth in the industry (CX 877). The firm manufactured and sold both trade-named and generic drug products. Whereas Warner-Lambert's market strength was probably most notable in proprietary drugs, Parke, Davis focused almost exclusively on the sale of ethical products.<sup>7</sup> In addition to detailing specialty brand name items to physicians, Parke, Davis also sold generic drugs as commodities to hospitals and retail pharmacies.

[5] Parke, Davis showed mixed financial returns for a several year period preceding the acquisition. While profitable throughout the 1960's, the company's performance worsened after 1966, the year the patent expired on its antibiotic, Chloromycetin. The drug had also received bad publicity as a result of certain fatal side effects. In 1965 Chloromycetin had accounted for about 30 percent of all Parke, Davis' sales (CX 3707). By 1967, Parke, Davis faced stiff competition from producers of generic Chloromycetin (choramphenicol) and reduced its prices 33 percent across the board. Between 1965 and 1970, Parke, Davis' profits had fallen by 50 percent and it had been unable to develop any new high-profit making drug to take the place of Chloromycetin. It appears that at least part of Parke, Davis' problem related to management and marketing.

By the time of the merger, Parke, Davis had fallen from its former leading position in the pharmaceutical industry. In terms of sales, Parke, Davis had ranked second in 1950 and as recently as 1960 was in third place among all manufacturers of ethical drugs. In 1969, the year before the merger, it ranked eleventh in ethical drugs and fifteenth in all drugs. Its board of directors had reduced dividends from \$1.45 in 1965 to \$1 in 1967 and to \$0.60 in 1970.

On the other hand, Parke, Davis was certainly not a failing company. It has never had an unprofitable year. By 1968, the sales of Chloromycetin already had been reduced to a considerably smaller share of total sales than they had been in 1966, and sales of the remainder of Parke, Davis' product line were increasing at an annual rate in excess of 10 percent (CX 3707). By the time Parke, Davis was acquired in 1970 by Warner-Lambert, stockholder investment had risen to \$216 million and the company had no outstanding long-term debt.

<sup>7</sup> As has already been noted, Parke, Davis had minimal proprietary drug sales. A new entrant must invest huge sums, acquire marketing expertise and develop a wide distribution system including food stores in order to compete successfully in the proprietary market (Tr. 2224, 3184-90, 3637). Parke, Davis studied its marketing capabilities and abandoned several proposed proprietary products concluding that it lacked the kind of product lines and financial resources necessary to become a viable proprietary competitor (Tr. 3576-79).

However, a decrease in the price of Parke, Davis' stock from \$24.75, its 1969 low, to a low of \$13 in early 1970 made that company an obviously attractive acquisition candidate.

#### THE ACQUISITION

According to the testimony of Mr. Stuart Hensley, who became President of Warner-Lambert in 1967, Warner-Lambert's management had become concerned about the company's ethical drug division, Warner-Chilcott. Its growth rate was considerably behind the rest of the industry, its products were antiquated, lacked uniqueness and patent protection and "with the advent of increasing generic types of products, appeared to be quite vulnerable" (Tr. 2640). It had spent \$6 to \$10 million annually on R&D since 1961 or 1962 without producing any new chemical entity. By 1969, according [6] to Hensley, it had become clear that Warner-Lambert needed to find "a partner that would broaden our base and give us a better opportunity of more product lines in which to do research, increasing our opportunity for discovery of new drug entities, [and] that we were likely to be faced with curtailing the basic research of Warner-Chilcott, maybe even cutting it out \* \* \*." and maintaining only a development group (Tr. 2642-43).

To Warner-Lambert's management, Parke, Davis possessed the attributes to be a partner that would broaden Warner-Chilcott's research base and would result in substantial savings in international operations (Tr. 2643-44, CX 912-F). Following a review of Parke, Davis and its recent earnings problem, Warner-Lambert officials believed that the company's performance had largely been due to management shortcomings, outmoded marketing and poor coordination between marketing and R&D (Tr. 2645, 3085, 3572-74, 3676).

After preliminary contacts, negotiations Warner-Lambert offered on July 30, 1970, to buy all Parke, Davis' stock in return for 6,600,000 shares of Warner-Lambert common stock. The Parke, Davis board of directors voted to accept the offer, rejecting a competing Revlon Company offer, and the transaction was completed on November 13, 1970.

#### ALLEGED RELEVANT MARKETS

The complaint alleges that the acquisition in question substantially lessened competition in drug manufacturing generally and the ethical segment. Respondent does not dispute the propriety of using an overall drug manufacturing market and an "ethical drugs" market for purposes of this case. In addition complaint counsel argue that twenty therapeutic end-use "submarkets" suffered a loss of actual or potential

competition because of the acquisition. The existence of thirteen of these subsidiary markets is not contested by respondent. These markets are:

- (1) oral decongestants
- (2) cough drops and lozenges
- (3) cold remedies
- (4) antihistamines
- (5) antacids
- (6) emollient/protective dermatological preparations promoted ethically
- (7) prenatal vitamins
- (8) ampicillin
- (9) urinary non-sulfa antibacterials
- (10) mouthwash
- (11) normal human serum albumin
- (12) immune serum globulin
- (13) tetanus immune globulin

[7] Complaint counsel failed to convince the administrative law judge that the remaining seven markets also exist as separate markets. These markets are:

- (1) thyroid preparations
- (2) anti-anginal drugs
- (3) cough remedies
- (4) bronchial dilators
- (5) irritant laxatives promoted ethically
- (6) antibiotics useful against gram-negative bacilli
- (7) anti-pseudomonas drugs

There is agreement between the parties that as to all asserted markets and submarkets, the nation as a whole is the appropriate geographic market or "section of the country." Although the complaint charged that among the asserted submarkets the merger would eliminate substantial *existing* competition in only five therapeutic submarkets, complaint counsel now claim there are eight such submarkets: thyroid preparations, cough remedies, cold remedies, cough drops and lozenges, bronchial dilators, irritant laxatives (ethical), emollient/protective dermatological preparations (ethical), and anti-anginal drugs. The remaining twelve submarkets involve contentions that Warner-Lambert or Parke, Davis was eliminated as a significant potential competitor because it was contemplating entry or already had a toehold position in a market where the other was a leading firm.

The administrative law judge dismissed allegations of anticompetitive effects with respect to all the markets and submarkets. Our

examination of the record leads us to conclude that a violation of Section 7 of the Clayton Act has been demonstrated with respect to five submarkets: thyroid preparations, cough remedies, cough drops and lozenges (actually a further submarket of the cough remedies submarket), normal serum albumin, and tetanus immune globulin. We find no violation with respect to the other asserted markets and submarkets.

In addition to vacating the findings of the initial decision with respect to the submarkets where we have found violations, we are vacating the entire initial decision and substituting our own findings with respect to the remaining markets as well. We do so in order to set forth with specificity the factual underpinnings of our decision since with respect to several submarkets the ALJ did not enter extensive findings.

We will first turn to the two principal markets in this case, overall drug manufacturing and its ethical drug segment, and then take up the allegations with respect to the twenty submarkets. [8]

#### I. DRUG MANUFACTURING AND ITS ETHICAL SECTOR

##### Preliminary Observations

The complaint in this matter alleges that the acquisition in issue may substantially lessen competition in drug manufacturing generally and in the ethical segment thereof. "Ethical drugs" are understood to be pharmaceutical products for which a doctor's prescription is required or which, although sold without a prescription, are primarily promoted to the medical profession and pharmacists. Ethical drugs, together with "proprietary drugs" (drug products advertised directly to the public and sold without need of a prescription), constitute all of the drug manufacturing market.

In its answer to the complaint filed October 15, 1971, respondent denied that either drug manufacturing in general or ethical drugs constituted appropriate "product markets" or "lines of commerce." However, on June 19, 1972, in an amendment to its answer, respondent withdrew this denial.<sup>8</sup>

At the outset we should note some reservation on our part in accepting the manufacture of "all drugs" and "all ethical drugs" as constituting product markets for this case. As so defined, these markets include literally thousands of separate, noncompeting pharmaceutical products. Mouthwashes are not substitutes for laxatives,

<sup>8</sup> In its brief on appeal, respondent characterizes the withdrawal of its original denial as "admitting, at least *arguendo*," the existence of these markets (Ans. Br. 2). Respondent argues however that concentration is too low and the market shares of the merged firms too small to present even a *prima facie* case with respect to these broad markets.

and antibiotics are not substitutes for tranquilizers. No manufacturer, including the firms involved here, sells a complete line of pharmaceuticals and it cannot be said that many manufacturers compete throughout even a broad portion of the spectrum of drug products. What evidence is in the record at most suggests the existence of an "all ethical drugs" market based on commonality of production and distribution techniques — in other words, a market defined in terms of interchangeable supply factors.<sup>9</sup> But the promotional skills needed to [9] advertise successfully and distribute efficiently proprietary drugs to the public are substantially different from those used in promoting ethical drugs to the medical profession. Also, the resources needed to develop and manufacture a product such as new mouthwash are different than those required in the development of new life-saving antibiotics. As noted *supra*, n.7, Parke, Davis considered but abandoned attempts to break into the proprietary field. Eli Lilly, which for years has been the leading seller of ethical drugs, ranked only 124th in proprietary drugs in 1969 (Comm. Find. 34). Conversely, Sterling Drug which was ranked first in proprietary drug sales that year ranked only 17th in the ethical market (*id.*).

We are not obligated, of course, to accept undisputed allegations in pleadings, including our own complaints, where we have doubt as to their validity at the time we finally consider the case. After the complaint in this matter issued the Commission decided *Sterling Drug, Inc.*, 80 F.T.C. 477 (1972) in which a broad market defined as the "health and beauty aids industry" was litigated. This market consisted in part of "all proprietary pharmaceuticals." In rejecting the health and beauty aids market definition, the Commission noted, *inter alia*, that there was little evidence in the record that firms specializing in some areas of proprietary drugs have the capability of diversifying into other areas of the proprietary drug field. "The record indicates, for instance, that there may be significant differences in the technology between production of external and internal proprietary medicines, the latter requiring less in the way of medical research, testing facilities, and techniques for quality control." *Id.* at 594.

However, our failure to be convinced of a common market consisting of all proprietary drugs in *Sterling* would not have foreclosed

<sup>9</sup> Ordinarily markets are defined in terms of "demand side" analysis, *i.e.*, examination of the demand for a product and the willingness of users to substitute other existing products for it. As alternative products become more substitutable their influence on a seller's price increases. In addition, however, the "supply side" of the market equation may be important. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 n.42 (1962). A firm may be limited in its power over price by the existence of firms which can readily switch production from non-substitutes to substitute products. Such firms also may be considered to constitute part of the market as they have sufficient resource flexibility to compete if profit opportunities beckon. Such a market may or may not be co-extensive with common definitions of an industry. See *Sterling Drug, Inc.*, 80 F.T.C. 477, 583-595 (1972), *The Budd Co.*, F.T.C. Dkt. 8848 (Aug. 29, 1975) slip opinion at 5 [86 F.T.C. 518 at 522]. Narver, "Supply Space and Horizontality in Firms and Mergers" 44 St. John's L. Rev. 316 (Spring 1970, spec. ed.).

complaint counsel in this case from attempting to make a record in support of the “all drug” and “ethical drug” market definitions had they been contested here. Consequently, we will assume that a sufficient showing of [10] resource flexibility could have been made to justify treating the drug industry and its ethical segment as product markets for purposes of this part of the case. Compare other cases where non-homogenous products have been treated as constituting a line of commerce, *e.g.*, *A.G. Spalding & Bros., Inc. v. Federal Trade Commission*, 301 F.2d 585 (3d Cir. 1962) (“athletic goods industry”); *United States v. Philadelphia National Bank*, 374 U.S. 321 (1963) (“commercial banking” consisting of a cluster services); *United States v. Bethlehem Steel Corp.*, 168 F. Supp. 576, 594 (S.D.N.Y. 1958) (“iron and steel industry”). “In those cases it was established or undisputed that resource flexibility existed or that the product groupings were sold as a full line by most firms.” *Sterling Drug, Inc.*, *supra*, 80 F.T.C. at 595, n.19; *British Oxygen Co.*, Dkt. 8955 (Dec. 8, 1975) slip opinion at 41 [86 F.T.C. 1241 at 1369]. [11]

#### Industry Concentration and Market Shares.

Prior cases striking down horizontal mergers have emphasized the degree of market concentration and the merging firms’ shares. “Statistics reflecting the shares of the market controlled by the industry leaders and the parties to the merger are \* \* \* the primary index of market power.\* \* \*” *Brown Shoe Co. v. United States*, 370 U.S. 294, 322, n.38 (1962). The assumption and primary concern is that undue concentration will enhance the opportunity of market leaders to engage in interdependent rather than competitive practices and thereby to control and regulate prices. Although various therapeutic end-use markets (denominated “submarkets” in this case) are highly concentrated, with respect to aggregate drug and ethical pharmaceutical sales there is little doubt that concentration is not at a high level. Stipulated DKK market share data,<sup>10</sup> establishes that four- and eight-firm concentration in the two broad markets in 1969 was as follows:

	<i>Ethical Drugs</i>		<i>All Drugs</i>	
	CR4	CR8	CR4	CR8
1969	26.10	44.01	23.76	39.39

These levels of concentration are well below the four-firm concentration ratio of 31 percent and eight-firm concentration ratio of 48 percent which the Commission in the *Sterling Drug* case found to be

<sup>10</sup> Davee, Koehlein, and Keating (DKK), a market research organization, compiles statistics on sales of pharmaceutical products. These statistics were stipulated by the parties to be accurate and reliable for purposes of this case (Comm. Find. 27).



“only a moderate degree of concentration,” 80 F.T.C. at 596, and the four-firm ratio of 35 percent and eight-firm ratio of 50 percent involved in *United Brands* where the Commission concluded that “in not one of the markets does an oligopoly exist.” *United Brands Co.*, F.T.C. Dkt. No. 8835 (May 14, 1974), slip opinion at 21 & n. 15[83 F.T.C. 1614 at 1709]. The administrative law judge in this case was fully justified, therefore, in finding that the record did not support a finding that the overall markets are characterized by substantial concentration (I.D. 30).

[12] Nor has the merger of Warner-Lambert and Parke, Davis materially changed the picture. In 1969, the year before the merger, Parke, Davis ranked 15th in the overall drug market with a market share of only 2.42 percent while Warner-Lambert ranked 12th with a 3.10 percent market share. In the same year, Parke, Davis stood 11th in the ethical market, with 2.90 percent, and Warner-Lambert was 15th with 2.31 percent of that market (Comm. Find. 34).

Plainly, this merger did not produce “a firm controlling an undue percentage share of the relevant market” and resulting in “a significant increase in \* \* \* concentration,” held to be *prima facie* unlawful in *United States v. Philadelphia National Bank*, 374 U.S. 321, 363 (1963) and later cases. By summing Warner-Lambert’s and Parke, Davis’ 1969 market shares to arrive at a *pro forma* projection of the merger’s effect on concentration, the merger would add about two percentage points to eight-firm concentration in the overall drug market and about one percentage point to eight firm concentration in the ethical drug market. No change would be noticed at the four-firm level. In fact, the stipulated market data showed that by 1971, the first full year after the merger, due to countervailing trends in the market, actual eight firm concentration was slightly less than it was before the merger in ethical drugs and the increases in other concentration ratios were barely perceptible:

	<i>Ethical Drugs</i>		<i>All Drugs</i>	
	<i>CR4</i>	<i>CR8</i>	<i>CR4</i>	<i>CR8</i>
1969	26.10	44.01	23.36	39.39
1970	26.29	44.43	23.80	41.38
1971	26.56	43.71	23.87	40.65

The same data show that in 1971 the merged firm ranked 4th in the overall drug market, with 5.27 percent of sales, and 5th in the ethical drug market with a 4.81 percent market share.<sup>11</sup>

In all other cases where effects on concentration were cited as

<sup>11</sup> By citing 1971 data, we are not suggesting that the presence of post-merger market share data is necessary in merger cases. However, in this case they are in the record and corroborate projections based in pre-merger market share data.

grounds for barring a merger, concentration ratios were considerably higher than they are here. In *Philadelphia National Bank, supra*, the merger created a bank having at least 30 percent of the market. In *United States v. Aluminum Co.* 377 U.S. 271(1964), the first two firms had over 50 percent [13] of the market. In *United States v. Continental Can Co.*, 378 U.S. 441 (1964) the six largest firms had 70 percent of the market. In *Stanley Works v. Federal Trade Commission*, 469 F.2d 498 (1972), the four-firm ratio was approximately 50 percent. In *Beatrice Foods Co.*, F.T.C. Dkt. 8864 (July 1, 1975) [86 F.T.C. 1] the four-firm ratio was over 40 percent—and climbing—in one market and over 50 percent in another market. In the absence of such concentrated markets, other factors such as a clear trend toward concentration substantially augmented by the merger were present. See *Brown Shoe Co. v. United States, supra*, 370 U.S. at 345; *United States v. Von's Grocery Co.*, 384 U.S. 270, 274, 277 (1966); and *United States v. Pabst Brewing Co.*, 384 U.S. 546, 551 (1966) (local markets also highly concentrated).

Complaint counsel argue that the drug industry is almost a “loose oligopoly” as defined in Kaysen & Turner, *Antitrust Policy* (1959), and point out that this definition was cited with approval by the Commission in *Kennecott Copper Corp.*, 78 F.T.C. 744, 922 (1971). According to Kaysen and Turner, “a loose oligopoly” is “a small number (less than twenty) of firms supplying 75 percent of the market, with no one supplying more than 10-15 percent and a fringe of smaller firms supplying the rest.” *Id.* at 922, n. 12. The DKK data indicate that the top 20 sellers possessed approximately 70 percent of sales in overall drugs and 75 percent of ethical drug sales (Comm. Find. 39, Table VIII). But complaint counsel fail to observe that in *Kennecott*, the Commission recognized that a “loose oligopoly” as defined by Kaysen and Turner was not a critical level of concentration.<sup>12</sup> The Commission found decisive in that case the fact that there was (1) a rapid growth trend among the leading firms outpacing the rest of the industry and (2) entry barriers already high were becoming more formidable indicating “that the industry is on the way to becoming highly concentrated” 78 F.T.C. at 922. The top four firms had increased their share from 15.8 percent in 1954 to 29.2 percent by 1967, and the top eight from 23.6 percent to 39.7 percent during the same period. *Id.* at 935. In view of this rapid trend, the Commission held that it “cannot stay its hand until the industry has in fact been transformed into a tight oligopoly,” *id.* at 922. In affirming the Commission’s order, the

<sup>12</sup> Subsequent studies by economists have tended to affirm the view that such a level of concentration is generally well below a critical level. See, e.g., Meehan & Duchesneau, “The Critical Level of Concentration: An Empirical Analysis,” 22 *Journal of Industrial Economics* 21 (1973) and authorities cited there.

Court of Appeals characterized this trend as a "phenomenal disproportionate growth" among the top firms. *Kennecott Copper v. Federal Trade Commission*, 467 F.2d 67,73 (10th Cir. 1972).

[14] In the overall drug markets, no such disproportionate growth among the top firms has occurred threatening to raise concentration levels to critical heights. What in fact has happened is that following World War II, medium-sized firms have grown far more rapidly than the industry leaders. According to Census data, companies in the 9-20 size group increased their market share of total shipments from 20 percent in 1947 to 33 percent in 1967 (the latest year prior to the merger in which Census data is available), whereas the share of the four largest firms declined and the next four remained fairly constant (CX 727).

Furthermore, the tables based on stipulated DKK data depicting the gains and losses in market rank and shares during the period from 1957 through 1971 for identified firms show that many leading firms have not been able to maintain their position in the markets. (Comm. Find. 31, Table I). With respect to the ethical line, the top four companies collectively accounted for 29.07 percent of sales in 1957. By 1969, the collective share of these former leaders had shrunk by nearly one-third to 20.74 percent. The same is true for the all drug line, with the 26.22 percent collective share of the four 1957 leaders having dropped to 18.42 percent by 1969. Moreover, without exception, each of the top eight ethical drug manufacturers in 1957 lost market share during the succeeding years. Parke, Davis is an example of a once leading firm that was unable to maintain its market share and rank. In 1971, the year after the merger, the Warner-Lambert/Parke, Davis combined ethical drug share was 4.81 percent which is less than Parke, Davis alone accounted for ten years earlier (RX 1863 Revised).

In addition to conventional concentration ratios, the degree of asymmetry in size among leading firms is another factor which economists consider in assessing the competitive structure of markets. A given level of concentration measured by aggregate market shares held by top firms may portend different market conditions depending upon whether firms within the grouping are relatively equal or quite disparate in size, with equality of size evidencing a more favorable climate for competition. Scherer, *Industrial Market Structure and Economic Performance*, 51-52 (1970); Mann, "Asymmetry, Barriers to Entry and Rates of Return in 26 Concentrated Industries," 8 *Western Economic Journal* 86 (1970). Here, the evidence shows a high degree of size uniformity. Looking at the ethical market in 1969, no firm had as much as a 7.5 percent share of the market; the difference between the first and the eight ranked firms was only about three percentage

points. Moreover, there is no sharp drop-off after the top eight, but rather a gradual tapering down in firm size so that the twentieth firm is still significant (Comm. Find. 22 & 34).

[15] Furthermore there has been no significant trend toward concentration in either the ethical drug or the all drug lines of commerce. As we observed in *Sterling Drug, supra*, 80 F.T.C. at 597 "The 4-firm concentration (based on value of shipments) in all pharmaceuticals (SIC 2834) for 1966 was 24 percent, a decline from the 1958 figure of 27 percent. Similar decline occurred between 1958 and 1966 in the 8-firm concentration ratio\* \* \* ." Data for more recent years does not substantially alter the picture.

In 1970, four-firm concentration was 26 percent in all pharmaceuticals (SIC 2834) and eight-firm concentration was 43 percent, both figures remaining below 1958 levels. Similarly in "Biological Products" (SIC 2831) four-firm concentration dropped from 44 percent in 1958 to 37 percent in 1970.<sup>13</sup> Eight-firm concentration remained at 59 percent, dropping from a 1966 high of 72 percent (Comm. Find. 39, Table IV):<sup>14</sup>

	CONCENTRATION IN SIC 2834 (Pharmaceutical Preparations)		CONCENTRATION IN SIC 2831 (Biological Products)	
	CR4	CR8	CR4	CR8
1947	28	44	38	51
1954	25	44	46	51
1958	27	45	44	59
1963	22	38	36	57
1966	24	41	46	72
1967	24	40	39	63
1970	26	43	37	59

Concentration ratios calculated from DKK data for both ethical drugs and all drug sales show a similar lack of increase (Comm. Find. 32, -Table II):<sup>15</sup> [16]

<sup>13</sup> The drug industry as defined in this case embraces two four-digit Census categories: SIC 2834, Pharmaceutical Preparations (total shipments in 1970 valued at \$6.028 billion), and SIC 2831 Biological Products (total shipments in 1970 valued at \$236 million).

<sup>14</sup> 1972 concentration ratios published by Census after the record was closed showed no significant increases in concentration despite the instant merger. Four-firm concentration has remained at the same level in both 2834 and 2831. Eight-firm concentration ratios increased one percentage point (to 44) in 2834 and dropped six percentage points (to 53) in 2831.

<sup>15</sup> Census figures are slightly different than DKK data for the following reasons among others: DKK figures are projections based on samples of drug store and hospital purchases only. Nursing homes and grocery stores are not sampled. Nearly 40 percent of proprietary drugs are sold to grocery stores and other non-drug store outlets missed by DKK. Therefore, Census figures are more inclusive in measuring the overall drug market which consists of both ethical (80 percent) and proprietary drugs (20 percent), although Census figures include shipments of veterinary drugs, which are not within the Complaint Counsel's definition of drugs. On the other hand, Census does not publish concentration ratios for the ethical sector and unlike DKK data, which are gathered on a line of business or product basis, Census data, particularly in annual survey years, are compiled only on an establishment basis, with the result that there is some over-inclusion and some under-inclusion.

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	<i>Ethical Drugs</i>		<i>All Drugs</i>		
	<i>CR4</i>	<i>CR8</i>	<i>CR4</i>	<i>CR8</i>	
1957	29.07	50.31	26.22	44.58	
1958	27.82	49.17	25.43	43.78	
1959	26.95	48.19	24.76	43.01	
1960	25.52	46.86	23.24	41.31	
1961	26.00	45.79	23.44	40.43	
1962	25.35	44.14	23.38	39.77	
1963	24.66	43.54	23.04	39.54	
1964	23.81	42.34	22.46	38.95	
1965	23.39	42.33	21.96	38.73	
1966	24.35	42.75	22.74	39.23	
1967	25.22	43.64	22.97	40.35	
1968	25.44	43.75	22.58	38.93	
1969	26.10	44.01	23.26	39.49	
1970	26.29	44.43	23.80	41.38	

[17] If we examine concentration levels beginning with 1963 as the base year—as urged by complaint counsel—the picture is not substantially different.<sup>16</sup> Although concentration levels have resulted in a net increase between 1963 and 1970, the increase has not been substantial. As indicated in the foregoing table, less than two percentage points separates the 1963 and 1970 concentration levels as calculated from DKK data. Census tabulation for 4- and 8-firm concentration ratios between 1963 and 1970 show a slightly more upward trend. Considering the picture presented by both DKK and Census data, the average rise was about two percentage points—not sufficient in our opinion to amount to a likelihood that in the foreseeable future concentration levels will reach a level which the Commission has heretofore considered unduly high. (See cases cited *supra*, pp. 12-13).

Complaint counsel argue that a type of “concentration trend” is evidenced by the fact that Census shows that the number of separate enterprises in the drug manufacturing industry declined from 1214 in 1954 to 910 in 1967 and to 738 by 1972. They rely on *United States v. Von's Grocery Co.*, 384 U.S. 270, 277 (1966) where one of the factors relied upon by the Court was a “rapid decline in the number of grocery

<sup>16</sup> In *Sterling Drug*, we examined concentration levels between 1958 and 1966—the most recent eight-year period prior to the merger in that case which occurred in 1966. Examining the merger here, which occurred four years later, suggests using a later base to determine whether there has been any “recent trend that threatens to transform an unconcentrated market into a concentrated market” *Sterling Drug*, *supra* at 598 (emphasis added). Cf. *Justice Department Merger Guidelines; Horizontal Mergers—7. Market With Trend Toward Concentration: “[A] trend is considered to be present when the aggregate market share of any grouping of the largest firms in the market from the two largest to the eight largest has increased by approximately 7 percent or more of the market [i.e. 7 percentage points] over a period of time extending from any base year 5-10 years prior to the merger (excluding any year in which some abnormal fluctuation in market shares occurred) up to the time of the merger.”* None of the concentration ratios for the two overall markets here increased as much as 7 percentage points whatever base year is selected.

store owners mov[ing] hand in hand with a large number of significant absorptions of the small companies by the larger ones." But in *Von's* it was apparent that even a small, one-store company could provide [18] effective competition to the outlets of big chains located in its immediate area. It is well known that in the drug industry there are a large number of fringe "repackaging houses," often controlled by physicians, that buy generic drugs from lowest-cost sources and resell them under their own brand names at much higher prices—frequently above prices charged by leading firms in the industry.<sup>17</sup> Many of the existing firms may come from this group which provides no competition. Complaint counsel themselves conceded below "virtually all the Census exits must have come from the ranks of small companies" and that such "decline in the population of small competitors" would not "be of competitive significance to an economist" (CPF 36). Indeed, their economist-witness, Dr. Schifrin, testified that he did not find any competitive significance in the drop in the number of drug firms standing alone. (Tr. 2201, 2373). The size of the fringe firms in the industry is indicated by the fact that DKK data for 1968-1969 shows that the 791st ranked firm had sales of only \$16,000. We reject the argument that this "depopulation" trend has any significance for purposes of this case.

Other objective measurements of industry position confirm the relatively low rank of the two companies. This evidence consists of a series of nonsales measurements of industry position in various categories of promotional activity and research expenditures.

The shares of Warner-Lambert (W-L) and Parke, Davis (PD) in ethical drug promotional activities in 1970 are summarized in the following tabulations (CX 3601-24):

	W-L	PD	W- L/PD
	<i>Share</i>	<i>Share</i>	<i>Share</i>
Detail calls	1.3%	2.9%	4.2%
Journal pages	2.6	2.0	4.6
Journal dollars	2.8	1.9	4.7
Direct mail ads	2.8	1.0	3.8
Direct mail dollars	2.9	1.2	4.1
Direct mail circulation	2.1	1.6	3.7

[19] The combined company accounts for a somewhat smaller share of each category than its combined ethical drug sales.

Of the Pharmaceutical Manufacturers Association's 1970 survey of

<sup>17</sup> By prescribing these brands, the stockholding physicians assure a market for the firm and dividends on their own investments at the same time. Measday, "The Pharmaceutical Industry," *The Structure of American Industry* (W. Adams, ed. 1971) at 168. Measday estimated there were 150 such firms.

its members' expenditures on ethical drug research, Parke, Davis accounted for 3.4 percent and Warner-Lambert 2.3 percent, for a combined share of 5.7 percent, which is approximately the same as the combined company's share of total ethical drug sales.

Complaint counsel argue that the loss of independence of a large firm like Parke, Davis in itself is likely to lessen competition in the drug field quite apart from any measurements of effects on concentration. The loss may be permanent, it is argued, by the fact there are substantial barriers to new entry<sup>18</sup> (Comm. Find. 29 & 30) that make it unlikely a new firm will arise in the foreseeable future to take Parke, Davis' place. Although Parke, Davis and Warner-Lambert are substantial companies in absolute terms and leading companies in a number of product lines, the overall drug and ethical drug markets are defined so broadly that there are no industry-wide dominant firms such as we find in automobiles, computers, or many other industries. Instead, the bulk of these two broadly defined markets are shared by 20 or more large, well-established firms with a number of smaller, but viable firms. We know of no economic theory that suggests that the reduction by one out of such a large number of competitors constitutes a *substantial* lessening of competition. The cases cited by complaint counsel on this point are readily distinguishable as concentration was higher making loss of one firm much more critical. *Crown Zellerbach Corp. v. Federal Trade Commission*, [20] 296 F.2d 800 (9th Cir. 1961) involved a merger between the largest firm in the market (51.5 percent) with the third largest firm (11 percent) in an industry with only four firms of any size 296 F.2d at 818. *Fruehauf Trailer Co.*, 67 F.T.C. 878 (1965) held unlawful the acquisition by the largest firm in the truck trailer industry (39.1 percent) of two substantial firms found to be "aggressive, well-managed, successful and growing, ranking third and sixth in the industry." 67 F.T.C. at 933. In *A. G. Spalding & Bros., Inc.*, 56 F.T.C. 1125 (1960), *aff'd*, 301 F.2d 585 (3rd Cir. 1962) the Commission held illegal a merger in an industry "dominated" by four firms between the second and fourth ranked firms. Clearly, the instant merger, which involves firms ranking 15th and 12th with 2.42 percent of 3.10 percent market shares in the overall drug market and similar shares in the ethical market is not comparable to those in the cited cases. As we held in *Sterling Drug, supra*, "[e]ven where there are substantial barriers to new entry \* \* \* it cannot be said \* \* \* that

<sup>18</sup> The average return on investment by members of the pharmaceutical industry ranged between 16 and 20 percent between 1958 and 1972, which placed it as the first or second most profitable manufacturing industry in the United States according to this Commission's Quarterly Financial Report series. (Manufacturing as a whole had average returns of 8.6 percent to 12.3 percent.) This indicates that the barriers to effective competition—due for the most part to patents, product differentiation, brand-name prescribing, and anti-substitution laws—are quite high. Complaint counsel concede that the acquisition has not *enhanced* such barriers.

horizontal mergers are *per se* or presumptively unlawful regardless of the smallness of the market shares" (p. 597).

Finally, complaint counsel argue that the low concentration ratios as measured across the overall and ethical drug markets "understate the real concentration of economic power in the industry" which is "to be found at the product rather than the industry level" (Rep. Br. 27,28). They contend that concentration levels in individual product lines are considerably higher, ranging typically from 70 percent to 90 percent for the top eight sellers. But this simply suggests that the overall drug and ethical drug markets are too broadly defined to be useful for purposes of analyzing the competitive effects of this merger. Complaint counsel cannot have it both ways. They cannot posit a market defined in terms of supply flexibility to include the output of non-substitutable drugs of both of the merging firms, characterize the merger in that market as entirely "horizontal," but then when measuring the degree of concentration ignore portions of the output of other firms doing business in that same market. The extent to which this merger had effects on concentration levels in therapeutic *end-use* product markets should be considered only in conjunction with claims of Section 7 illegality in the 20 submarkets in issue. To that subject we now turn. [21]

## II. THERAPEUTIC SUBMARKETS

### Thyroid Preparations

Individuals who are unable to secrete enough thyroid hormone to regulate adequately their bodies' metabolism must consume thyroid preparations to compensate for the shortage. This affliction, called hypothyroidism, can be remedied by the ingestion of either natural thyroid hormone, which is cleaned and desiccated hog or cow thyroid, or synthetic thyroid hormone, made by chemical synthesis.

Parke, Davis sells two natural thyroid products, "Thyroid USP," a generic product that meets the standards for dosage strength and processing set by the United States Pharmacopoeia, and "Thyroid Strong," also a generic product which is 50 percent more potent than Thyroid USP. Warner-Lambert also produces two thyroid hormones, both trade-named. They are "Proloid," a natural hormone, which differs from Parke, Davis' product in that it is derived only from hog thyroid and is "washed" more in order to remove more extraneous materials, and "Euthroid," a synthetic hormone, combining in a carefully measured amount the two ingredients basic to all natural hormones, T-3 and T-4, which are frequently found in irregular quantities in their natural state.



Despite their differences, it is apparent that all thyroid hormones are administered and used in substantially the same manner on nearly all hypothyroid patients to bring them up to normal (euthyroid) condition. See Comm. Find. 48-49.

Complaint counsel urge that all thyroid preparations, including both branded and unbranded products, comprise a single line of commerce for Section 7 purposes. The administrative law judge, agreeing with respondent's contentions, found that unbranded and branded thyroid preparations compete in separate economic markets on the grounds that "there are substantial differences in the way the two companies' products are manufactured, the customers and methods used in selling their products, the way they are priced, and since they are sold only on prescription of a physician, the way they are dispensed to the ultimate user" (I.D. 48). We agree with complaint counsel that the ALJ erred in concluding that there is not a single thyroid market.

Clearly the factors cited by the ALJ may be relevant in determining whether different thyroid preparations *may* be separated into different submarkets, but they do [22] not *compel* a division into separate lines of commerce if the products are functionally interchangeable to a significant degree. "The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). See also *United States v. Continental Can Co.*, 378 U.S. 441 (1964).

Respondent argues, however, that the different ways that unbranded and branded thyroids are dispensed to the ultimate use—makes *therapeutic* interchangeability irrelevant. It argues that individual physicians do not prescribe branded and unbranded thyroid interchangeably for patients; that physicians are fixed in their prescribing habits and do not abandon a product with which they have gained experience in favor of another. Respondent also contends, and the ALJ found, that unbranded USP thyroids (such as Parke, Davis') are "commodity" products sold to the *pharmacist* on a price basis, since prescriptions for USP thyroids generally do not specify a particular manufacturer's product. On the other hand, branded products (such as Warner-Lambert's Proloid and Euthroid) are promoted to the *physician* in an attempt to secure his specification of their brand name for thyroid prescriptions. Thus, it is argued that sales of branded and unbranded thyroid products are insulated from each other. In support, respondent cites testimony that the prices of branded products have not been a factor in manufacturers' pricing of unbranded thyroid products, and vice versa. It also notes that the price of Proloid

(Warner-Lambert's branded natural thyroid) is approximately twice that of USP thyroid, while the synthetic products are approximately four times the price of the USP thyroid. The retail price of a USP thyroid tablet is approximately one to two cents.<sup>19</sup>

Although there may be lack of price elasticity between branded and unbranded products at existing prices levels, we cannot assume that all physicians are so fixed in their prescribing habits that a substantial increase in the existing price differential between branded and unbranded thyroids would never cause some shift toward more prescriptions of [23] the lower-priced USP thyroids. Warner-Lambert's own advertisement to physicians (CX 910) assumes that prescribing habits are not immutable as it stresses the "smoothness" with which patients may be converted to its branded synthetic from other natural or synthetic thyroid preparations, whether branded or unbranded. Also, we can take notice that some physicians, even if a minority, are conscious of price differences between generic and branded versions of the same or similar preparations since a substantial number will prescribe generic drugs despite promotions of branded varieties. We see no reason to believe that price would never enter into some physicians' decisions in the area of thyroid medication. It is not necessary that two products battle inch for inch on the same turf in order for them to be in the same market. *L. G. Balfour Co. v. Federal Trade Commission*, 442 F.2d 1, 10-11 (7th Cir. 1971).

We therefore reject respondent's contention that branded and unbranded thyroid preparations must be placed in separate product markets. This conclusion is consistent with the practices of the industry's leading market researcher (DKK) which furnishes data on these products to drug company clients under a single classification called "thyroid preparations" without a breakdown between branded and unbranded varieties. Respondent's own documents in the record treat "thyroid preparations" as a single economic market (CX 912G, 3663-64).

As indicated in Table IX of our Findings, the top four suppliers of this \$20 million market accounted for about 80 percent of sales in 1969 and 82 percent in 1970, measured in dollars. Warner-Lambert's share was approximately 20 percent, placing it second in the market in 1969 and third in 1970. Parke, Davis' share was approximately 4.5 percent, placing it fifth in the market. However, it is obvious that Parke, Davis' share of the market is understated since its thyroid products were sold at prices one-half to one-fourth the price of Warner-Lambert's

<sup>19</sup> Although respondent stresses that these are not high prices in any event, compared to many other pharmaceuticals, it should be noted that hypothyroidism is usually a chronic condition that requires medication on a daily basis throughout the life of a patient. Hence, price differentials of these products are not necessarily trivial, especially when low-income patients must continually take the medication.

branded thyroid preparations of equivalent dosage form. The other market leaders also sold branded products. Based on unit sales, therefore, Parke Davis' market share would have been much higher.

Nevertheless, even using dollar sales as the sole criterion, the acquisition made Warner-Lambert the number one [24] seller and substantially increased four-firm concentration from 82.4 percent to 87 percent. This increase in an already high level of concentration, amounts to a substantial lessening of competition. The high level of concentration and the substantial market shares involved outweigh any countervailing considerations based on the fact that Warner-Lambert's thyroid products are specialty products sold at a different price level than Parke, Davis' USP product and that entry barriers may not be as high in this submarket as other therapeutic submarkets involved in this case. The continued presence of Parke, Davis' product in the hands of an independent marketer is important to assure prescribing physicians the choice of Parke, Davis' lower-priced product. Even if the identity of the USP thyroid prescribed for a patient is unknown to the doctor, Parke, Davis as an independent competitor may have contributed to keeping the price of USP thyroid lower than it might have been. We find, therefore, that the assimilation of Parke, Davis into Warner-Lambert has violated Section 7 in this product market.

#### Cough Remedies

Cough remedies come in different forms—liquid syrups, tablets and capsules, and cough drops and lozenges—and are marketed in different ways. Some cough remedies are advertised directly to consumers and are sold as proprietary items. Others are also sold over the counter, but if promoted at all by brand name, are promoted mainly to physicians (“ethical OTC” cough remedies). Another group are available only by prescription of a physician. Cough remedy sales altogether are quite large, exceeding \$200 million in 1969.

Most of Warner-Lambert's cough remedy products are proprietary cough drops or lozenges. These include Smith Brothers Cough Drops, Hall's Mentho-Lyptus Cough Tablets, Listerine Throat Lozenges (which although promoted for relief of sore throats is conceded by Warner-Lambert to be classifiable also as a cough remedy) and Listerine Cough Control Lozenges. Parke, Davis markets prescription cough syrups, unbranded OTC ethical cough syrups, branded cough syrups and “Parke, Davis' Medicated Throat Discs” which is sold over the counter next to higher-priced cough lozenges.

Unlike its position with respect to the thyroid preparation market, respondent does not argue that cough remedies of any particular form

must be divided into separate “branded” [25] and “unbranded” markets. Rather its contention here is that all cough drops and lozenges constitute a market separate from all cough syrups. The administrative law judge agreed, pointing *inter alia* to the fact that “cough drops and lozenges” are asserted as one of the twenty submarkets which complaint counsel argue has been adversely affected as a result of the merger (I.D. 27).

We reach a contrary conclusion. The fact that a grouping of products may constitute a submarket is not dispositive of the question whether they may be a part of a broader market. *United States v. Greater Buffalo Press*, 402 U.S. 549, 552-53 (1971); *United States v. Phillipsburg National Bank*, 399 U.S. 350, 359-60 (1970); *United States v. Grinnell Corp.*, 384 U.S. 563 (1966); *United States v. Aluminum Co. of America*, 377 U.S. 271, 276-77 (1964). Also the fact that there may be substantial physical differences in the products does not prevent them from being grouped in one product market if there is a significant degree of overlap in their usage. *United States v. Continental Can Company*, 378 U.S. 441 (1964) (glass containers and metal containers grouped together in one market); *Beatrice Foods Co.*, F.T.C. Dkt. 8864, July 1, 1975 [86 F.T.C. 1] (paint brushes and paint rollers found to constitute a single market).

It may well be, as respondent contends, that drops and lozenges are most often used for minor coughs and that physicians rarely recommend a cough drop or lozenge but are more likely to prescribe a liquid or tablet preparation. Nevertheless, we believe that all “cough remedies” describe a proper market. The record shows that consumers use syrups as well as drops and lozenges to treat their own cough symptoms. Syrups, lozenges, and drops (and tablets and capsules) often contain the same ingredients and perform the same general function—symptomatic relief of coughs.<sup>20</sup> Between the mildest tickle and the most severe cough is a range of disorders that can be treated by products in any of these categories. Moreover, the best relief for coughs is an antitussive. The preferred antitussive compound now available is dextromethorphan, which, being non-narcotic, is readily available in drops, lozenges, tablets and liquids.

[26] Even when a physician is consulted and prescribes a stronger and more expensive product, such as a syrup containing the narcotic codeine, or larger amounts of antihistamine or decongestant than is found in over-the-counter products, there can be a degree of competitive substitutability. To the extent the anticipated price of a

<sup>20</sup> Tr. 750-52, 3752. Compare, for example, the ingredients listed for Cosanyl DM cough syrup with Ludens Cough Drops. Both contain substantial parts of cocillana (CX 1528, 1605). Similarly, Nilcol Tablets, Super Anahist Antitussive Cough Syrup, Listerine Cough Control Lozenges, and Vicks Cough Silencers cough drops all contain dextromethorphan (CX 1495, 1497, 1594, 1601).

prescription item enters into a person's decision whether to medicate himself (or a coughing child) or call upon a physician to prescribe a product, demand will be transferred from one group of products to another with some regard to the price of these products. We have no doubt that if the sale of cough drops and lozenges were banned, sales of the other types of preparations including syrups would increase as a result. Considering these and other record evidence cited in our Findings (Comm. Find. 63) we find that cough preparations constitute a single line of commerce.

The cough remedies market is sufficiently concentrated to be concerned with the loss of a significant firm through acquisition. The four largest firms had 45 percent of sales in 1969 and the eight largest 63 percent. Warner-Lambert's share of the market in 1969 was 4.4 percent. Parke Davis' sales represented 4.2 percent of the market in 1969. The acquisition raised four-firm and eight-firm concentration nearly three percent (Comm. Find. 64 and 65). In addition, as we recite in our Findings at greater length, both Warner-Lambert and Parke, Davis were taking vigorous steps to expand their product lines and improve their positions in the market (Comm. Find. 67). Thus, in 1969 and 1970 Warner-Lambert had under development or had just begun marketing Silenex, Smith Brothers cough syrup, and two lozenges, Coughlets and Listerine Cough Control Lozenges. Sales of some of these products appear to reflect only slightly in the market share figures given for 1969. Its 4.4 percent market share in 1969 was an increase of nearly 25 percent over its 1968 market share and could possibly have risen to 6.8 percent for that year if imported products had been included in the universe and market share tabulations since Warner-Lambert imported \$5.2 million in sales of Hall's Mentho-Lyptus tablets in 1969 which were not included.

Parke, Davis also undertook efforts to reformulate many of its products. On September 1, 1970, it introduced Cosanyl-DM Cough Syrup (Improved Formula) with certain up-to-date ingredients. This new product was selling at the rate of \$100,000 per month at the time of the acquisition. [27] In sum, the record suggests the beginning of a growth trend that could have elevated to even greater importance the two competitors who combined in late 1970. In view of existing concentration in the market, the merger removed substantial competition from the market.

Entry barriers in this market have not been demonstrated to be so low that this judgment requires revision. The presence of over a hundred actual, but *de minimis* competitors does not contradict the evidence of entry barriers (Comm. Find. 66). To be an *effective* competitor in this market, it is simply not enough to buy some bottles,

fill them with a cough syrup, and sell them for a profit. To make substantial sales, great amounts of money and marketing ability are required to convince physicians or consumers as to the desirability of a new cough remedy.

### Cough Drops and Lozenges

Cough drops and lozenges have particular characteristics and uses which set them apart as a separate submarket from other types of cough remedies. They are more portable than liquid cough remedies and can be purchased without a physician's prescription. Respondent does not dispute the existence of a "cough drops and lozenges" market, nor does respondent dispute that Warner-Lambert was a leading firm in this market with a 27 percent market share and that Parke, Davis' share was almost 3 percent based on dollar sales.

Warner-Lambert markets two cough drops—Smith Brothers Cough Drops and Hall's Mentho-Lyptus Cough Tablets. It also sells Listerine Throat Lozenges and Listerine Cough Control Lozenges, both of which it classifies as part of this market. Parke, Davis has one product in this market—Medicated Throat Discs.

The administrative law judge summarily dismissed the allegation of violation in this submarket essentially on the ground that Parke, Davis' Medicated Throat Disc is an "outmoded" product. (I.D. 46).<sup>21</sup> The record does not support this conclusion.

[28] In the two years prior to the merger, Medicated Throat Discs increased in sales from \$1.4 to \$1.5 million and Parke, Davis officials anticipated a further increase in both dollar and unit sales in 1970 (CX 1574).

Although Medicated Throat Discs were not distributed through food stores (as some cough drops and lozenges are) it was a successful over-the-counter product in drug stores. Although a Parke, Davis survey showed that Medicated Throat Discs ranked number six among lozenges in terms of dollars in sales to drugstores, it ranked "number one in disc volume, number two in packages sold \* \* \*. One out of every four throat lozenges sold in drugstores in 1968 was a MTD [Medicated Throat Disc]" (CX 1573, 1575). Again this is an example of where a market share based on dollars understates the volume of Parke, Davis sales. Medicated Throat Discs was ranked number six in dollar sales but number one in dosage volume because it is priced considerably lower than the brand name lozenge products. The Parke,

<sup>21</sup> Respondent makes the additional argument that Medicated Throat Discs is not a viable competitive product because it does not taste good. This is unconvincing—and particularly ironic in view of Warner-Lambert's "Tastes bad \* \* \* twice a day" theme in its advertising campaign for Listerine mouthwash which is an apparent attempt to create the impression that bad taste is characteristic of high quality in over-the-counter pharmaceuticals.

Davis survey report notes that whereas Medicated Throat Discs retailed at around 37 cents for a box of 60 discs, Merck's Screts retailed at 98 cents for a box of 55 discs, and Squibb's "Spec T" lozenges were packaged with 24 discs for \$1.98.

Concentration is high in this submarket. In cough drops, the top three firms possess over 80 percent of sales. In cough lozenges, the four largest sellers represented 76 percent of sales to hospitals and drugstores. Total sales of cough drops and lozenges amounted to over \$50 million in 1969. (Comm. Find. 70 & 71). Against this background, we find that the merger violated Section 7 by significantly adding to an already high level of concentration and removing an important competitive factor.

#### Cold Remedies

There is, of course, no known cure for the common cold. What is referred to here as cold remedies are preparations directed at relieving against the *nasal symptoms* of a cold, *i.e.*, nasal swelling, stuffiness or excessive nasal secretions. There is an industry and public recognition of a distinction between "cold remedies" and "cough remedies." Preparations which are indicated for coughs (including coughs due to colds) because of the presence of antitussives or [29] expectorants are considered "cough remedies" in the industry and for purposes of this case.<sup>22</sup> Warner-Lambert markets several cold remedies which together represent approximately 4 percent of sales in the market. Its rank in the market was 9th in 1969 and 10th in 1970. The administrative law judge found that Parke, Davis had at most 0.16 percent of the market, a *de minimis* amount insufficient to find a violation based on elimination of actual competition.

Complaint counsel contend, however, that the ALJ erred by not recognizing Parke, Davis' prescription cough syrups, Benlyn Expectorant and Ambenyl Expectorant, as cold remedies in addition to their classification as cough remedies in this case. (Addition of these products would bring Parke, Davis' market share up to two percent.) They argue that these cough preparations are also cold remedies because they contain an antihistamine, which may have some drying action on the nasal passageway. However, it is undisputed that antihistamines do not combat nasal *congestion* resulting from a cold virus and therefore should not be considered a specific treatment against colds, although at one time they were and a few physicians still

<sup>22</sup> The industry also recognizes a group of products called "cough and cold preparations" which are products usually having an antitussive and/or expectorant as well as an oral nasal decongestant (RX 1495, Tr. 3307). For purposes of this case, these products have been included in both the cold remedies submarket and the cough remedies submarket.

prescribe them for symptoms of colds. According to expert consensus today, antihistamines are useful in allaying the nasal dripping only if there is an allergy involved. The advertising, package inserts, and labels for both Ambenyl and Benylin indicate them only for the "control of cough due to cold or allergy."

Complaint counsel's expert witness in pharmacology, Dr. Standaert, testified that physicians who would still use Ambenyl and Benylin as cold remedies would be doing so "[i]n spite of the best teaching of we pharmacologists" that antihistamines are not effective in such situations [30] (Tr. 924). Data derived from the National Disease and Therapeutic Index strongly confirm the observations of this and other expert witnesses who so testified. A sampling of office-based physicians show that from 1969 through the first half of 1973, they prescribed Ambenyl Expectorant for cough approximately 87.9 percent of the time, and for cold only 6.6 percent of the time (RX 2229). Similarly, during the same time period, these physicians prescribed Benylin Expectorant for cough approximately 87.3 percent of the time, and for cold only 5.3 percent of the time (RX 2231).

Ambenyl and Benylin were properly excluded from this market by the ALJ. As a result, it is clear that no violation of Section 7 has been demonstrated since Parke, Davis' sales of cold remedies amounted at most to 0.16 percent of the market in 1970. Furthermore, the record does not show that Parke, Davis has any unusual competitive potential in this market.

#### Oral Decongestants

Decongestants shrink the swollen lining of the nose and decrease the activity of glands in the area. In 1969, Warner-Lambert ranked 9th in the oral decongestant market with a 5.15 percent market share. In 1970, it ranked 8th with 5.19 percent. Parke, Davis entered this submarket in 1970 with sales of Cosanyl-DM Cough Syrup (Improved Formula) of \$368,000 (all of which were also included in both the cough remedies market and the cold remedies market<sup>23</sup> by complaint counsel), which represents 0.18 percent of the market. This submarket is moderately concentrated but there are a large number of other toehold firms similarly situated.

Complaint counsel argue that the ALJ in dismissing this submarket ignored the estimate of Parke, Davis officials that the company could reach an annual volume of about \$1 million in this market (CX 1725) and that its toehold position of \$368,000 sales at the end of 1970 was reached after just four months of sales. But even if the \$1 million

<sup>23</sup> The product was also included in the cold remedies market as it contains an oral decongestant. See preceding footnote.



projection were reached this would amount to only 0.5 percent of the 1970 oral decongestant market.

As in the cold remedies market, we find no indication that Parke, Davis had unusual capabilities of becoming a substantial competitor in this market. [31]

#### Antihistamines

Antihistamines are materials which act against histamine, a compound produced in the body which is released when an individual is exposed to material to which he is allergic. Antihistamine sales were \$36 million in 1970. The market is concentrated with Parke, Davis being the second largest seller with 23.5 percent of the market with sales of its antihistamines, Benadryl and Ambodryl. Warner-Lambert had minimal sales which were discontinued in 1969.

The principal evidence relied upon by complaint counsel to show that Warner-Lambert was a significant potential competitor is the fact that it had filed Abbreviated New Drug Applications (ANDA's) with the FDA on five single-ingredient antihistamine products. The difficulty with this argument is that there are a large number of toehold firms already in the market. In addition, dozens of firms had also filed New Drug Applications or Abbreviated New Drug Applications for antihistamines. From 1970 to 1973, at least 110 ANDA's were filed by 52 companies not counting Warner-Lambert's.

The Commission finds there is insufficient evidence that Warner-Lambert was a legally significant potential entrant in this submarket.

#### Bronchial Dilators

The drugs employed to give symptomatic relief of constriction of the muscles of the air passages (bronchospasm) caused by asthma, bronchitis and emphysema are generally referred to as bronchial dilators. *Oral* preparations are used primarily in maintenance therapy and to abort mild attacks. *Injectable* preparations such as Adrenalin (epinephrine) are used when other medication has failed or would be useless. They are used only as a last resort because they must be injected and have substantial side effects. Over 99 percent of Warner-Lambert's sales are accounted for by oral preparations. Almost 99 percent of Parke, Davis' sales are accounted for by injectable epinephrine or ephedrine. Contrary to complaint counsel's contentions, the record clearly shows that oral and injectable bronchial dilators are not in the same market as they are not interchangeable in medical usage (Comm. Find. 85 and 86). Reasonable interchangeability in use is

the test, not whether the effectiveness of one product may obviate the need for the other which is used only as means of a last resort.

[32] Excluding sales of injectable dilators, the sales of Parke, Davis are *de minimis* (\$18,000 or 0.3 percent of the market). Warner-Lambert's sales of \$10 million represent approximately 18 percent of the market. Elimination of actual competition is therefore not significant.

Complaint counsel argue that among oral bronchial dilators, Parke, Davis could have expanded its toehold position, citing the fact that shortly before the merger it negotiated with Premo Pharmaceutical Laboratories for the possible purchase of almost one million oral bronchial dilator tablets for resale. There is no showing, however, of what one million tablets would represent in dollar sales, and there is no particular reason to believe the company would be successful in expanding its present *de minimis* position in the market very greatly. Sixteen firms among the top 50 ethical companies marketed bronchial dilators at some point during the period after 1958 without attaining as much as two percent of the market in any year. There appears to be no shortage of firms in a position comparable to Parke, Davis.

#### Irritant Laxatives (Ethical)

Laxatives fall into two groups, those promoted directly to the public and those promoted "ethically" to pharmacists and physicians. Regardless of their methods of promotion, all laxatives are usually shelved side-by-side in retail pharmacies.

Laxatives contain ingredients which pharmacologically are classified as irritants, salines, bulk formers, oils and mild emollients and softeners. In recommending laxatives, doctors take these distinctions into consideration. For instance, irritant laxatives are more dependable in clearing the bowels, but can also cause distressing cramps. Emollients and mineral oil laxatives are generally milder, however, a number of laxatives combine different ingredients so a laxative may not always be classified as clearly falling in a particular pharmacological category. In fact the record convincingly shows that the lay consumer does not recognize "irritant" laxatives as a distinct category. This is significant since most laxatives, even ethical laxatives, are sold without doctors' recommendations. However, even among physician-directed uses of laxatives the evidence is not entirely persuasive that *irritant* laxatives constitute a recognizable submarket since the principal characteristic of irritant laxatives (that they are "sure fire" in their effects as one pharmacologist witness phrased it) is also shared by saline laxatives (Comm. Find. 94). The ethical [33] laxative sold by Warner-Lambert, "Agoral," which is classified as an irritant laxative

by complaint counsel as it contains the irritant phenolphthalein, is not classified by DKK in its surveys as an irritant laxative apparently because it contains emollients (mineral oils) as well and is promoted as a gentle laxative.<sup>24</sup> Under complaint counsel's market definition and treatment of Agoral as an irritant laxative, Warner-Lambert would be ranked eighth in 1969 with 2.8 percent of sales, and Parke, Davis seventh with 3.7 percent.

Even accepting complaint counsel's market definition, we are unable to conclude that they have demonstrated by a preponderance of the evidence that their allocation of Agoral to the alleged irritant laxative submarket is appropriate. Nor is there a violation in any overall laxative market. Neither party had as much as 2 percent of the overall market or ranked within the top 12 firms.

#### Emollient/Protective Preparations Promoted Ethically

Ethical emollient and protective dermatological preparations are creams, lotions, and ointments used to treat extremely dry skin conditions which require a high degree of lubrication. Such preparations are promoted to dermatologists.

[34] It is clear that no violation has occurred in this market. Universe sales totaled \$16 to \$17 million in 1969 and 1970 with Parke, Davis' share about one-tenth of one percent. Warner-Lambert's market share has been between 12 and 13 percent, by reason of its sales of Lubriderm.

After the hearing, complaint counsel contended for the first time that substantial existing competition has been eliminated. They tendered a new market share tabulation showing Parke, Davis with a 1.3 percent market share, arguing that the tabulation submitted during the hearing had erroneously omitted sales of Aeroderm, a Parke, Davis product which the marketing survey firm DKK had placed in the "All Other" subdivision of Ethical Dermatologicals rather than the "Emollient and Protective" classification. Complaint counsel appeal from the ALJ's failure to include sales of Aeroderm in determining Parke, Davis' share of the market and failing to find a violation in this line of commerce. However, the record indicates that DKK's classification was correct as Aeroderm is more a hand and body massage rub lotion used in hospitals (CX 2221, 2230). It is not promoted to dermatologists for use outside hospitals by patients with extremely

<sup>24</sup> Agoral's label stresses its gentle effects, its palatability since it is marshmallow or raspberry flavored, and describes the product as a bedtime laxative. Complaint counsel's pharmacology witness agreed that he would not consider a "sure fire" irritant laxative to be a type which is to be taken before retiring for the night (Tr. 952). Agoral also comes in unflavored form, which contains no irritant ingredient, but is a mineral oil laxative.

dry skin conditions and is not competitive with preparations used for this purpose (Tr. 3133-36).

#### Anti-Anginal Drugs

Although there were no formal findings concerning anti-anginal drugs in the initial decision, it appears that the ALJ believed there was no violation in this area on the ground that complaint counsel had defined the market too broadly by including anti-anginal products that work in therapeutically different ways (I.D. pp. 33, 43).

Anti-anginal drugs are defined as drugs designed to relieve the chest pains of angina pectoris. Complaint counsel's market definition purports to include both those products which are designed to abort an anginal attack and those which are designed for long-term prophylaxis. The former include sublingual (under the tongue) nitroglycerin, sublingual isosorbide dinitrate, and amyl nitrate. The latter consist of oral pentaerythritol tetranitrate (PETN), beta blockers, and oral forms of isosorbide and sustained-release nitroglycerin preparations. Parke, Davis markets only sublingual nitroglycerin; Warner-Lambert markets only PETN under the trade name Peritrate. Respondent contends that preparations used to *abort* an anginal attack, principally sublingual nitroglycerin, do not belong in the same market as preparations which serve only a long-term prophylactic purpose. Complaint counsel contend that competition between these regimens nevertheless exists—as the patient may either wait for an anginal attack to improve or occur, in which case he would be relegated [35] to using a sublingual nitrate, or he or his doctor may try to reduce the number of attacks in advance by regular doses of long-acting oral nitrates or beta blockers. Complaint counsel also produced evidence that as many as 10 percent of nitroglycerin users take large quantities—up to 50 or 100 pills daily—in hope of avoiding feared attacks, thus using sublingual nitroglycerin as a prophylactic drug (Comm. Find. 103).

Considerable evidence was placed in the record and relied upon by both parties in support of their respective positions, consisting, *inter alia*, of medical practices by physicians, comparative efficacy of oral nitrate regimens (a subject of intense debate in the profession), promotional literature of oral nitrates, price disparity and lack of price sensitivity between the long and short-acting anti-anginal products. We find, however, that is unnecessary to determine whether these two types of products constitute a single end-use product market, since even assuming they do, the record would not support a finding of violation.

Total purchases of all anti-anginal drugs by U.S. drug stores and

hospitals were \$55.1 million in 1969 and \$61.8 million in 1970. Warner-Lambert's 1969 sales of its oral nitrate, Peritrate were \$23 million, giving it a market share of 41.8 percent. Because of inroads by the earlier appearance of beta blockers in the U.S. market, Warner-Lambert's share dropped to 36.5 percent in 1970 (\$22.6 million in sales). In 1971, Warner-Lambert was for the first time in many years passed in rank as the leading seller by American Home Products, the seller of Inderal, a beta blocker. Parke, Davis sales of sublingual nitroglycerin amounted to \$66,000 in 1969 and \$130,000 in 1970, giving it a market ranking of 0.1 percent and 0.2 percent respectively, clearly *de minimis* shares.

Complaint counsel argue, however, that market shares based solely on dollar sales grossly understate Parke, Davis' sales since its short acting product is priced much lower than long-acting products in the "market." Warner-Lambert's Peritrate for instance sells for 18 times as much per pill as does Parke, Davis' nitroglycerin. According to complaint counsel, in a "pill universe" computed on the same data Parke, Davis' market share would have risen to over 11 percent. However, it is not shown to us how this high figure was arrived at even assuming one pill of nitroglycerin is equivalent [36] therapeutically to one pill of Peritrate.<sup>25</sup> But further, unlike some other products involved in this case, dosage forms (pills here) are not therapeutically equivalent. According to complaint counsel's witness, the effectiveness of oral nitrates, such as Peritrate, ranges from 6 to 12 hours per pill (Tr. 663). Nitroglycerin's duration is in the order of 20-40 minutes per pill (Tr. 656)—a difference in ranges of duration by (exactly) a factor of 18. Complaint counsel's "pill universe" approach therefore must be rejected as arbitrary. Peritrate costs 18 times as much as nitroglycerin but lasts 18 times as long. Also, there is no coverage in complaint counsel's calculations of Inderal—the beta blocker which has made sizeable inroads into the market and which propelled American Home Products in first position in the market in 1971.

Nor is there sufficient basis for predicting that Parke, Davis would substantially improve its *de minimis* market position in an anti-anginal drugs submarket. Its market share in this submarket has historically been small. (This is not an atypical performance for a Parke, Davis generic product.) It is true that Parke, Davis constantly evaluates its generic product line and has added products to it over the years. Among the products it considered adding to that line was PETN. But Parke, Davis determined not to add PETN because it felt that there was little generic demand for this product; it is a highly

<sup>25</sup> Complaint counsel base their calculations on exhibits which were not put in the record or the rejected exhibit file or otherwise described in the briefs.

controversial drug; and it has only a "possibly effective" rating by the FDA (Tr. 3582-83). Even if PETN had been available to Parke, Davis for generic marketing, there is no particular basis for finding that Parke, Davis would have become an important factor in the alleged anti-anginal drugs submarket. There are many companies that are existing competitors in the anti-anginal drugs submarket. DKK reported sales by over 40 companies in 1970 and by over 50 companies in 1971. Among the sellers with small market shares were many large drug companies, all of which were at least as capable as Parke, Davis of expanding their market positions.

In conclusion, we find there is insufficient evidence to find a violation of Section 7 in an anti-anginal drugs submarket. [37]

#### Antacids

Antacids neutralize excess stomach acid resulting from peptic ulcers, heartburn and other causes of gastric distress. The antacids market, as defined for purposes of this case, encompasses all types of antacid products, including ethical OTC products and proprietary products such as Roloids and Tums. Warner-Lambert manufactures Gelusil, an ethical preparation, and Roloids and Bromo Seltzer, which are both proprietary products, and ranks second in the antacids market. Its sales amounted to \$48.4 million, which represent 18.5 percent of this \$261 million market in 1969. Parke, Davis manufactured three outmoded generic ethical antacid products, with combined sales of \$10,000. Complaint counsel does not dispute that Parke, Davis had no future in the antacids market on the basis of its existing outmoded products, and that it would have had to develop a new modern antacid product to be an effective competitor. Respondent accepts complaint counsel's all-inclusive submarket definition, but denies that the merger has removed Parke, Davis as a significant potential entrant.

The record shows that between 1966 and 1968, Parke, Davis formulated liquid and solid dose antacid preparations; however, complaint counsel's own witness, Dr. Aquiar (a Parke, Davis employee until 1970), testified that he was informed by his superior, Dr. Wheeler, "there was no marketing interest in [the antacids]" (Tr. 1807) which had no unique qualities. While complaint counsel also refer to 1969 proposals to allocate minimal amounts of time to product development which could have embraced further antacid work in addition to work in other areas, no appreciable further work was undertaken, and following a review of the antacid field in the spring of 1969, the company decided against expending any further effort in this general area.

Moreover, unlike Parke, Davis, which had no proprietary distribution

or consumer advertising expertise, there were 14 companies among the nation's top 100 advertisers which had substantial proprietary drug sales and already had products in the antacids market but were not among the top eight sellers. These toeholders were undoubtedly more capable than Parke, Davis of becoming significant competitors in the proprietary segment of the antacid market. Complaint counsel in fact concede that Parke, Davis was one of 13 companies with the ability to surmount barriers existing in the market (App. Br. 82).

[38] In conclusion, the Commission finds that the record fails to show that Parke, Davis was more likely than others to expand into the antacid market. No probable substantial lessening of competition has been shown.

#### Prenatal Vitamins

In 1969, the prenatal vitamin market was \$14.6 million, and concentrated in structure, with the top four firms (Parke, Davis, ranking second with 15 percent of sales) accounting for 57.3 percent of the sales. In 1969, Warner-Lambert's prenatal vitamin, Calcisalin, occupied a *de minimis* position in this market with 0.3 percent and \$64,000 in sales volume. After the complaint issued, the company withdrew the product from the market, rather than reformulate it to meet new FDA requirements. Calcisalin was a market failure apparently because the excessively large tablet had to be taken six times rather than once daily.

Although Warner-Lambert was capable of reformulating Calcisalin into a once-a-day preparation, it states it did not do so because it viewed the market as relatively unattractive for entry. Warner-Lambert's lack of interest in the prenatal vitamin market is consistent with its low interest and activity in the entire vitamin field. DKK reported its total sales of all vitamins in 1970 as \$53,000, including \$46,000 in reported sales of Calcisalin. In view of the lack of subjective evidence of Warner-Lambert's intent to re-enter this market, complaint counsel state that they do not stress this market an appeal. Our findings also set forth reasons why objective considerations make it unlikely that Warner-Lambert is a likely entrant into this market (Comm. Find. 120-121). No violation of Section 7 has been demonstrated in this market. [39]

#### Antibiotics Useful Against Gram-Negative Bacilli

The ALJ rejected this group of products as a relevant market and found, in any event, no lessening of competition. Complaint counsel

appealed on both points. However, we find the evidence fully supports the ALJ's conclusions.

Microorganisms causing infections are classified by scientists into several categories. One of those classifications is "gram-negative bacilli." There are many different bacilli falling within the "gram-negative" category and different diseases result from such bacteria. (The term "gram-negative" simply refers to a negative result on a common diagnostic test devised many years ago by a scientist named Gram). These diseases, or infections, may be treated by antibiotics or other drugs such as sulfonamides depending upon the infecting organism. An antibiotic may be active against a particular gram-negative bacillus, but not against other disease-causing organisms, such as "gram-positive bacilli" or "gram negative cocci." Most important for purposes of determining the validity of grouping these antibiotics as a relevant market is the fact that the preferred drug for a specific gram-negative infection will not be just any one of the twenty or so different antibiotics or chemotherapeutic agents active against one or more gram-negative bacilli. Selection of the proper drug, which may not always be an antibiotic, requires consideration of many factors: The infecting agent, the seriousness of the patient's condition, whether he is allergic to a particular antibiotic or drug, the site of the infection, and possible other factors.

Thus, despite the label given this alleged submarket, "antibiotics useful against gram-negative bacilli" does not define a group of products that appear to substantially compete *inter se* in any given situation. A good example of this are the antibiotics sold by the partners to this merger that fall within this market definition. Warner-Lambert [40] has sold only one antibiotic, Coly-Mycin, which, in injectable form, has been used mostly for certain urinary tract infections and, in topical preparations, for use for "swimmer's ears." The evidence shows that the "antibiotics effective against gram-negative bacilli" sold by Parke, Davis are Chloromycetin, ampicillin, tetracycline, and Paromycin which are preferred and used for other diseases. According to authoritative guides published to assist the practicing physician in selecting appropriate antimicrobial therapy, there is no circumstance in which Coly-Mycin is an alternate first choice with any of Parke, Davis' antibiotics and rarely are any listed together as possible alternative drugs if the drug or drugs listed as first choice should not be given for any reason.

The only situation where many of the antibiotics in this alleged market are perhaps interchangeable in practice is where initial therapy is necessary in infections which are suspected to be due to gram-negative organisms pending completion of culture tests to identify the



infecting organism. Even here the overlap in use appears to be more theoretical than real for the merging firms' products. Parke, Davis' Chloromycetin would not usually be used in such situations because of its sometimes fatal side-effects.

Although antibiotics in general might qualify as an industry-type market, there is no recognized industry or group of firms that specialize in manufacturing "antibiotics useful against gram-negative bacilli" to the exclusion of other antibiotics.

However, even if we accept "antibiotics useful against gram-negative bacilli" as defining a single product market for antitrust purposes (despite the doubts we have expressed), this merger would have no adverse effect on competition based on market shares considerations. In 1970, Parke, Davis combined sales accounted for a market share of 5.31 percent giving it a seventh in ranking. Warner-Lambert's sales in 1970 accounted for a market share of 0.66 percent. The combined effect of these market shares is a *de minimis* increase in concentration and precludes a finding that existing competition is likely to be substantially lessened by the merger in this alleged submarket. In fact, the evidence indicates that concentration has been decreasing and the number of companies marketing two important antibiotics with gram-negative activity, ampicillin and tetracycline, has been increasing.

[41] It also appears unlikely that Warner-Lambert would be one of the companies most likely to expand its position in this purported market. Its sales have been declining due to displacement by new and superior antibiotic products. Warner-Lambert is not regarded as a leading antibiotic developer. (Tr. 1316-17, 1321; Tr. 2949-52). It did not discover Coly-Mycin, its sole antibiotic product, has no antibiotic NDA's on file, has no antibiotic manufacturing facilities, and has no research capability for elaborating new antibiotics.

We agree with the ALJ that no lessening of competition in this alleged market is indicated.

#### Ampicillin

Ampicillin is a broad spectrum, semi-synthetic penicillin. The term "broad spectrum" refers to the fact that the drug is effective against many different kinds of microorganisms. There is no dispute that "ampicillin" describes a proper product market. Ampicillin was patented by Beecham, a British company, and sold in the United States by Beecham and licensed by Beecham to Bristol Laboratories and Bristol-Myers Co., ("Bristol"). Bristol has, in turn, sublicensed Squibb-Beechnut and American Home Products' Wyeth Division. In addition to Parke, Davis, which purchases ampicillin from Bristol in finished

dosage form, Ayerst Laboratories Division of American Home Products and Lederle distribute ampicillin which they purchase in dosage form from Beecham. A number of other companies also sell ampicillin without license, as the validity of the ampicillin patent has been successfully attacked.

Parke, Davis commenced marketing ampicillin in 1968 and has achieved a number 4 ranking in the market. Its 1970 sales of \$10.4 million gave it an 11.7 percent market share. The top four sellers are estimated to have controlled 95 percent of the market in 1970. Warner-Lambert has never sold ampicillin.

Complaint counsel appeals from the ALJ's finding that there is no basis for finding that Warner-Lambert was a potential entrant into this market. They cite the fact that during the period 1968 to March 1970, Warner-Lambert approached Beecham, and its licensee Bristol, about the possibility of obtaining rights to market several antibiotics including ampicillin. However, no agreement was ever reached, and Warner-Lambert's primary interest was in obtaining marketing rights to other, newer, antibiotics. Although complaint counsel contend that Warner-Lambert's interest was cut short only by the negotiations to acquire Parke, Davis, there is contemporaneous evidence indicating that what interest Warner-Lambert had in ampicillin was [42] not strong.<sup>26</sup>

Furthermore, the objective evidence strongly suggests that companies selling other antibiotics were more likely entrants into this market which by 1970 was opening up to sellers of generic ampicillin. In contrast to these companies, as previously noted Warner-Lambert had little experience in antibiotics. Loss of one among many such potential entrants would not substantially lessen competition.

#### Anti-Pseudomonas Drugs

*Pseudomonas aeruginosa* is a species of gram-negative bacilli which can cause life-threatening infections in a severely burned or leukemic patient as well as minor urinary tract and eye and ear infections. Unlike the "antibiotics useful against gram-negative bacilli," complaint counsel define this market to include not only antibiotics but other drugs effective against this organism. This permits them to claim the merger has eliminated Parke, Davis as a potential entrant since just prior to the merger Parke, Davis had filed an application with the

<sup>26</sup> For instance, an early 1969 Warner-Lambert memorandum identified numerous "[p]roblems of marketing ampicillin in the black." It pointed out that there were already five competitors which has a "head start," that all competitors had made "20% price cuts in Oct. 1967," that "[s]elling a 'commodity' vs. a 'specialty' item would require W-L to undercut already stringent prices to carve any volume for itself," that "[c]omplete oral and injectable lines must be marketed (Squibb's mistake) and a potent detailing force enlisted," that "[p]roduction toolup makes W-L cost-cutting unlikely." (CX 2486).

Federal Government for a license to market an anti-pseudomonas vaccine. Parke, Davis' only other "anti-pseudomonas" product was an ophthalmic preparation to which polymyxin B had been added to reach pseudomonas in the eye and which gave the company only a *de minimis* share of this market. Warner-Lambert's share was 9.4 percent, down from 16.9 percent in 1969, resulting from sales of Coly-Mycin antibiotic products. (By 1971, its share was down to 6.1 percent because of the introduction of newer drugs in this field).

The ALJ rejected any violation in this submarket because each of the two companies' products is designed for specific purposes and neither would eliminate uses of the other. We agree. The proposed Parke, Davis vaccine is intended to be [43] used with severe burn and leukemic patients in the hope of getting ahead of the development of infection by building a resistance in the patient. The vaccine is not intended to be used in lieu of any antibiotics as it is an immunological product. Nevertheless, complaint counsel argue that there would be cross-elasticity of demand between such an anti-pseudomonas vaccine and antibiotics, citing the testimony by respondent's medical expert, Dr. Finland, that the vaccine may, if proved successful, make the use of anti-pseudomonas antibiotics "antiquated" for burn patients (Tr. 2985). But that is not a sure test for cross-elasticity of demand. The invention of the automobile made the horse-drawn carriage antiquated, but no one would seriously contend that today competition or "cross-elasticity of demand" still exists between the two. No doctor would forego using a life-saving immunizing vaccine on burn patients because an antibiotic could be used as a last resort. Nor would Warner-Lambert have any incentive to withhold the vaccine from the market, since its only antibiotic, Coly-Mycin, is not widely used on burn patients (Tr. 2527-31). We find no lessening of potential competition here.

#### Urinary Antibacterials

The complaint identifies as an end-use submarket for this case "urinary antibacterials (non-sulfa)." These are defined by complaint counsel as drugs used in the treatment of urinary tract infections but exclusive of sulfonamides, antibiotics and urinary analgesics. While respondent in its answer admitted the propriety of this definition, the evidence at the hearing clearly established that short-acting sulfonamides are not only therapeutically interchangeable with other urinary antibacterials, but are now considered the drug of choice for acute urinary tract infection (Tr. 851-52, 1314-15, 3257). Complaint counsel themselves admitted this. (Tr. 140). Although respondent does not seek to change its concession as to the market definition, preferring to

argue the relevance of sulfonamides only on the issue of competitive injury, we believe analysis would best be aided by redefining the market to include sulfonamides. *Cf. General Foods Corp.*, 69 F.T.C. 280, 411 n.5 (1966).

[44] As so redefined, Hoffman La Roche and Morton Norwich companies dominated the market sharing nearly equally 70 percent of total sales (60 million). Warner-Lambert ranked third with 9.2 percent of sales. Parke, Davis had only \$70,000 in sales, or 0.1 percent of the market.

Although complaint counsel have objected to giving consideration to post-acquisition actions by respondents throughout other parts of this case when it favors respondent, in this submarket they rely almost entirely on post-acquisition evidence (indeed, post-complaint evidence) in arguing there has been elimination of Parke, Davis as a potential competitive force. They cite the fact that in March 1973, Parke, Davis introduced a new urinary antibacterial "nitrofurantoin" to its generic line and that factory sales were nearly \$50,000 in the first year of marketing.

Since there is no evidence in the record as to total industry sales of urinary antibacterials for 1973, there is no way of ascertaining Parke, Davis' market share in that post-acquisition year. But relating Parke Davis' 1973 sales to 1970 industry sales of \$60.4 million as reported by DKK, Parke, Davis would still have only a *de minimis* market share (0.1 percent of the market). Even if we assume that a Parke, Davis independent of Warner-Lambert would have made a better showing than is indicated by its 1973 sales, it is doubtful that the merger can even be characterized as combining a "leading" company in the market with a potential entrant in view of Warner-Lambert having a market share below 10 percent. *The Budd Company*, F.T.C. Dkt. 8848 (Aug. 29, 1975 slip opinion at 18 [86 F.T.C. 518]).

Also we would have to consider other post-merger developments such as the new sulfonamide antibacterial compound, trimethoprim-sulfamethoxazole, which was approved for marketing in the latter part of 1973 specifically for urinary tract infections (Tr. 1317-18). Studies performed in this country showed that it was more effective than sulfonamide. Also the patent on nitrofurantoin expired in 1969 or 1970. Approval to market it can now be secured under the abbreviated NDA procedure. This procedure is also available and has been widely used for securing marketing approval of the short-acting sulfonamides.

In addition to the top 8 suppliers and Parke, Davis, 59 companies reported sales of urinary antibacterials as early as 1969. All these facts would seem to overshadow Parke, Davis' introduction of generic

nitrofurantoin in 1973 insofar as it might indicate a loss of potential competition resulting from the merger.

#### Mouthwash

[45] With 48 percent of this \$185 million market (1970), Warner-Lambert ranked first. In addition to Warner-Lambert, the other leading mouthwash companies are: Procter and Gamble (Scope); Johnson and Johnson (Micrin); and Richardson-Merrill (Lavoris). Parke, Davis had four non-branded mouthwash products packaged and marketed only for institutional use. Total sales in 1970 were only \$29,000.

Complaint counsel argue that the initial decision ignores evidence that Parke, Davis gave serious consideration to the development and marketing of a proprietary mouthwash throughout the 1960's. These efforts, however, led to a decision not to market such a product. After a review of past development work, the director of marketing explained in a 1969 memorandum that the "primary reason for our decision is that it would take a considerable amount of money to effectively establish this product with the consumer. Unfortunately, within the last couple of years, the market has been literally flooded with new mouthwash preparations (*i.e.*, Micrin, Scope, Colgate 100, etc.) as well as the old standbys, Lavoris and Listerine. In our opinion, we could spend our advertising and promotion dollars more effectively in other product areas" (CX 2723). No further work was done in the mouthwash area.

In addition to this lack of subjective interest, objective considerations make it unlikely that Parke, Davis was a likely potential entrant. In order to achieve significant market penetration, substantial package goods merchandising, advertising, and distribution expertise is required.<sup>27</sup> Parke, Davis had never developed any of these. We find no basis to find a violation of Section 7 in this submarket. [46]

#### Human Blood Fractions—Normal Serum Albumin Immune Serum Globulin, Tetanus Immune Globulin

Normal serum albumin, immune serum globulin, and tetanus immune globulin are three out of some 25 or 30 different products that can be derived from human blood by a fractionation process. Normal serum albumin is used to assist in the regulation of the volume of circulating blood and as a source of protein nutrition. Immune serum globulin is used in preventing a number of human diseases. Tetanus

<sup>27</sup> While substantial advertising expertise is a prerequisite to success, it is not a guarantee. Thus, despite great expenditures, Warner-Lambert was unsuccessful in efforts to introduce two new mouthwashes—Reef and Sterisol—and Colgate-Palmolive failed to establish Colgate 100 as one of the leading brands.

immune globulin is used to provide immediate treatment to persons sustaining tetanus-prone injuries and who are not known to be immune to tetanus (Comm. Find. 147). Respondent does not dispute that each is a relevant line of commerce.

Blood fractions are generally considered "biologicals" and are regulated by the Federal Government's Bureau of Biologics ("BOB"). Blood fractionation involves a complex manufacturing process. The technical requirements include facilities that are estimated to cost \$2 million, which must be operated at a freezing temperature or below and requires special testing to assure quality control. BOB requires any manufacturer of therapeutic blood fractions to obtain a license to produce and another to sell. Once produced, blood fractions are marketed in the same manner as drugs—to hospitals, drug stores, and physicians.

Parke, Davis manufactures and markets each of these blood fraction products as well as others, and is a leading firm in two of them: In normal serum albumin (human) it ranked number one in 1969 with sales of \$2.4 million which gave it a market share of 34 percent. In tetanus immune globulin (human) it ranked number two with 28 percent of the market, \$701,000 in sales. In immune serum globulin (human) it was only the fifth largest seller with 7 percent of the market with sales of \$712,000.<sup>28</sup>

Warner-Lambert did not manufacture any of these or other blood fractionation products prior to the merger. However, in 1969, Warner-Lambert acquired Elizabeth Biochemical Laboratory which operated a multi-State chain of blood collection centers which distributed plasmas to industrial buyers such as blood fractionation companies. Elizabeth was the Nation's leading supplier of industrial blood plasma [47] (CX 257). Elizabeth's plasma was thus a raw material for blood fractionation. Despite indications that some blood fractionators do not consider ownership of blood banks as advantageous, ownership by a blood fractionation company would assure the latter a source of plasma when supply on the open market is scarce.

Complaint counsel argue that prior to the merger Warner-Lambert was a potential entrant into blood fractionation in entering these markets. In March 1969, when Elizabeth Biochemical was acquired, Warner-Lambert began laying the groundwork for a merger proposal with Cutter Laboratories, a blood fractionation company. An offer was later made but was turned down by Cutter. It is clear that Warner-Lambert viewed an acquisition of Cutter as a means of entering the field of human blood fractions and would have added business "closely

<sup>28</sup> The market-shares are based on open-market sales. They do not include contract fractionation work done for the American Red Cross or other non-profit institutions.

related to the efforts of Elizabeth Biochemical" (CX 2878; Comm. Find. 156).

Failing in its efforts to acquire Cutter, Warner-Lambert next turned to Squibb, another blood fractionation product supplier, investigating the possibility of Squibb manufacturing a line of blood products for Warner-Lambert to distribute. However, negotiations ceased in December 1969 because Squibb did not have manufacturing time available. Respondent's officials testified that these negotiations were conditioned upon a joint R&D program with Squibb for *new* blood fraction products and that this was its primary interest and that in any event Warner-Lambert was not seriously interested in selling blood fractionation products. However, the documentary evidence shows that the two areas of interest were not considered dependent upon each other. Consideration concerning Squibb supplying blood fraction products to Warner-Lambert for resale continued after it became certain that there would not be a joint *research* program. (CX 2887; CX 2891-92; CX 2105). We find the testimony unpersuasive in light of this documentary evidence.

We think there was a reasonable probability that Warner-Lambert would have eventually entered these important blood fraction markets, if not by *de novo* entry into fractionation itself (or by acquisition of a small company) then by distributing such products supplied to it by a fractionator. In view of its new position in 1969 as a supplier of plasma and the interest manifested thereafter in entering the blood fractionation business, the potential competition represented by Warner-Lambert was uniquely important. Considering the very [48] high concentration—four firm ratios exceeding 90 percent (Comm. Find. 150)—and the undisputed entry barriers in these markets, we find that in acquiring Parke, Davis, a leading firm in two of these markets (normal serum albumin and tetanus immune globulin), Warner-Lambert eliminated itself as a source of future competition that could have had a significant procompetitive effect. We find a violation of Section 7 in these two markets. [49]

### III. CONCLUSION

Viewing this acquisition in terms of the entire drug industry and its major segment, ethical drugs, there has been no showing of violation of Section 7 of the Clayton Act. As we said in *Sterling Drug, Inc.*, *supra*, 80 F.T.C. 477, 598, in the absence of a merger which produces a firm controlling an undue percentage of the market under consideration and results in a significant increase in concentration in that market, "something more than mere 'horizontal' of a merger must be shown \* \* \* [A]n important consideration is whether there is a recent trend

that threatens to transform an unconcentrated market into a concentrated market or whether the merger adds to or threatens to entrench existing concentration." Among aggregate sales of all drugs or "ethical drugs" (which represent 80 percent of all drug sales) concentration has not been high and there has been no trend threatening to change this picture.

This is not to say that price competition flourishes in most drug product submarkets. It clearly does not as indicated by the fact that the drug industry consistently enjoys one of the highest profit rates among all manufacturing industries. But lack of price competition is the result of a number of factors, including barriers to entry, that are in no way affected by this acquisition save where concentration has been unduly increased or entrenched by this merger in specific therapeutic submarkets.

In only three specific submarkets did these two drug companies compete with the result that substantial existing competition between them has been eliminated: thyroid preparations, cough remedies, and the cough drops/cough lozenges submarket. In two additional submarkets—normal serum albumin and tetanus immune globulin—important potential competition has been lost. Thus, in five submarkets altogether, competition has been substantially diminished by this merger in a manner that violates Section 7 of the Clayton Act.

#### IV. RELIEF

Complaint counsel have argued that if we find a violation of Section 7 in *any* line of commerce resulting from respondent's stock acquisition of the Parke, Davis [50] company, divestiture of the stock would be the appropriate relief. In *United States v. du Pont & Co.*, 366 U.S. 316 (1961), the Court decreed complete divestiture of the unlawfully held stock, saying (366 U.S. at 330-31):

Divestiture has been called the most important of antitrust remedies. It is simple, relatively easy to administer, and sure. It should always be in the forefront of a court's mind when a violation of §7 has been found.

The court also said that "complete divestiture is peculiarly appropriate in cases of stock acquisitions which violate Section 7" (*id.* at 328).

On the other hand, where the offending line or lines of commerce constitute a relatively small proportion of the entire business of the acquired corporation, partial divestiture may be appropriate if competition can be effectively restored in the affected markets. *Federal Trade Commission v. Pepsico, Inc.*, 47 F.2d 24, 29 (2d Cir. 1973); *United States v. Reed Roller Bit Co.*, 274 F. Supp. 573, 584-592 (W.D. Okl. 1967); *Union Carbide*, 59 F.T.C. 614, 659 (1961), *United*



*States v. CIBA*, 1970 Trade Cases ¶ 73,269 (S.D.N.Y. 1970) (consent decree).

We shall enter an order adopting the preceding findings of violation, and require the parties to submit a supplemental memorandum addressed to the issue of appropriate relief in this matter in light of the Commission's decision, including the issue of what relief is necessary and sufficient to restore competition in the submarkets in which violations have been found.

The parties shall submit a proposed form of order and memorandum within 30 days from date of service of the Commission's order, and may reply to each others' filings within 10 days of service of the filings upon them.

#### FINDINGS OF FACTS AND CONCLUSIONS OF LAW

[1] On June 30, 1971, the Commission issued its complaint against respondent charging it with having violated Section 7 of the Clayton Act, as amended (15 U.S.C. §18), in its acquisition of all or substantially all of the stock of Parke, Davis & Company. After the issuance of the complaint and the filing of respondent's answer, hearings were held before a duly designated administrative law judge of the Commission and testimony and other evidence in support of and in opposition to the allegations of the complaint were received into the record. In an initial decision filed August 2, 1974, the administrative law judge found the charge of violation of Section 7 of the Clayton Act had not been sustained by the evidence and ordered that the complaint be dismissed.

The Commission having considered the appeal of counsel supporting the complaint from the initial decision and the entire record in this proceeding and having determined that the appeal should be granted and that the initial decision should be vacated and set aside, now makes its own findings as to the facts, conclusions drawn therefrom, all of which, together with the accompanying opinion, shall be in lieu of the findings, conclusions and order contained in the initial decision. [2]

#### JURISDICTIONAL FACTS

1. Warner-Lambert Company (Warner-Lambert), respondent herein, is a corporation organized and existing under the laws of the State of Delaware with its principal office and place of business located at Morris Plains, New Jersey.

2. Prior to November 13, 1970, when it was acquired by Warner-Lambert, Parke, Davis & Company (Parke, Davis) was a corporation organized and existing under the laws of the State of Michigan with its principal office and place of business located at Detroit, Michigan.

3. At all times relevant to this proceeding, Warner-Lambert sold and shipped, and is now selling and shipping, products in interstate commerce throughout the United States and was and is engaged in commerce as "commerce" is defined in the Clayton Act.

4. At all times relevant to this proceeding, Parke, Davis sold and shipped products in interstate commerce throughout the United States and on November 13, 1970, and prior thereto, was engaged in commerce as "commerce" is defined in the Clayton Act.

5. On November 13, 1970, pursuant to an agreement and plan of merger dated August 25, 1970, Warner-Lambert acquired ownership of all or substantially all the stock of Parke, Davis in return for 6,600,000 shares of Warner-Lambert common stock.

#### RELEVANT MARKET AND LINES OF COMMERCE

6. The relevant section of the country within which to view the merger of Warner-Lambert and Parke, Davis is the entire United States.

7. There are a number of lines of commerce alleged to be relevant in considering this merger. They are as follows:

(a) The overall drug market. This asserted market consists of medicines, both pharmaceutical and biological, in dosage form and are limited in this proceeding to those for human use. Included in this market are ethical drugs and so-called proprietary drugs. Proprietary drugs are not a separate line of commerce relevant for consideration in this case, other than as a part of the overall drug market, described above. These are products manufactured and sold by the drug industry and which are promoted [3] principally to the consuming public. They may include products for which a prescription may often be written by a physician, but which may also be sold over-the-counter without a prescription.

(b) Ethical drugs. These drugs for which a prescription from a physician is required, or which, although sold over-the-counter (OTC) without a prescription, are primarily advertised and promoted by the drug industry to the medical, pharmacy and allied profession. . These ethical drugs are a relevant line of commerce for consideration in this case.

(c) In addition, counsel in support of the complaint assert that there are 20 separate submarkets of the overall drug market which include either ethical or proprietary drugs and which constitute distinct end-use product markets and must be considered individually in considering this merger.

## ACQUIRING CORPORATION: WARNER-LAMBERT

8. Warner-Lambert's history dates back to 1856, the year in which William R. Warner founded an ethical drug business in Philadelphia, which was acquired by Pfeifer Chemical Co. in 1908. In 1916 the stock of Richard Hudnut, a New York cosmetics manufacturer, was acquired and from 1920 to 1955 the combined business was known as Warner-Hudnut, Inc. Following a merger with the Lambert Company of St. Louis in 1955, the firm name was changed to Warner-Lambert Pharmaceutical Company and in 1970 simplified to Warner-Lambert Company.

9. The major portion of Warner-Lambert's research facilities, ethical pharmaceutical manufacturing facilities and the executive offices are located in Morris Plains, New Jersey. Proprietary pharmaceutical products are manufactured at other plants.

10. In 1969, prior to the acquisition of Parke, Davis, Warner-Lambert's sales were \$808 million and total assets were \$572 million. In 1969, its total domestic sales were \$540 million and its total domestic assets were \$366 million. Its sales were divided about equally among professional and consumer products and products sold internationally. In 1969, professional products, which included all products promoted to the medical profession, accounted for 36.1 percent of total sales, while consumer products (which included proprietary pharmaceutical products) accounted for 35.9 percent, and international sales 28.0 percent of total sales. Approximately 10 percent of the total of all sales for 1969 were accounted for by ethical drug sales.

[4] 11. Warner-Lambert over the years has enjoyed substantial growth in the drug industry. Its trade name products have become very familiar to the medical profession. The advertising behind such products as Listerine, Bromo Seltzer, Super Anahist, Smith Brothers Cough Drops, Roloids have made them household names and commonly are among the leading products in their markets. In addition, Warner-Lambert has been able to use these popular trade names to sell associated products, such as toothpaste, breath spray and throat lozenges.

12. Warner-Lambert utilizes both print and electrical medium to promote its products. These include direct mail, billboard, shelf-talkers displays, television, radio, newspapers, magazines and professional journals. In 1968 Warner-Lambert spent approximately \$80 million for domestic advertising; in 1969 approximately \$93 million and in 1970 approximately \$126 million for domestic advertising. In 1970 Warner-Lambert was the largest drug and cosmetic advertiser in the country and the fifth largest advertiser among all companies.

13. Warner-Lambert engages substantially in research and development programs. In 1969 it spent approximately \$11 million for ethical research and employed about 320 persons in this endeavor. Warner-Lambert likewise engages in research and development work with its foreign operations and derives benefits in this country from this overseas research and development. Warner-Lambert also engages in research and development work in support of its proprietary drug products which amounted to approximately \$2 million in 1970.

14. Warner-Lambert also employs a highly capable staff of 3,000 sales representatives in the United States serving various markets. It is a very marketing-oriented company, with an able promotional staff, skilled packaging experts and market planners.

#### ACQUIRED CORPORATION: PARKE, DAVIS

15. Parke, Davis has long been a famous ethical pharmaceutical company. Since the company was founded in 1866, its research and development has resulted in major contributions to pharmacy and medicine. Parke, Davis' executive offices and the largest of its ethical and proprietary facilities are located in Detroit, Michigan. Research facilities are centered in Ann Arbor, and Detroit, Michigan, while biological products are manufactured principally at Rochester, Michigan.

[5] 16. At all times relevant to this case, Parke, Davis has manufactured and sold pharmaceutical, biological, medical-surgical and related health care products in the United States and throughout the free world. Nearly all of Parke, Davis' pharmaceutical products were and are ethically promoted. It has been known in the pharmaceutical industry as a "broad line" house, meaning that its salesmen, in addition to detailing specialty items to physicians, also sell generic drugs as commodities to hospital and retail pharmacies. Pharmaceutical and biological products accounted for 41.7 percent of total Parke, Davis' sales in 1969, while medical-surgical products were 13.8 percent and international sales were 42.0 percent of all sales.

#### PRE-MERGER PERFORMANCE AND PROSPECTS OF PARKE, DAVIS

17. The record shows that by the time of the merger, Parke, Davis had fallen from its former preeminent position in the industry. Parke, Davis had ranked second in 1950 among all manufacturers of ethical drugs. However, by 1969, the year before the merger, it ranked eleventh. Its market share in the ethical drug line dropped from 6.02 percent in 1960 to only 2.90 percent in 1969.

18. In the years just before merger, Parke, Davis planned to

expand into proprietary markets using its broad range of consumer products. To this end a special Consumer Products Marketing Department was established in the latter half of 1969. However, these plans did not materialize into any significant entry in the proprietary field.

19. Parke, Davis' drop in market rank and share is matched by similar declines in its performance as measured by various financial indicators. From 1965 to mid-1970, Parke, Davis' net income fell approximately 50 percent from just under \$40 million to less than \$20 million. Its earnings per share dropped from \$2.25 in 1965 to approximately \$1 per share in the twelve-month period ending June 30, 1970. Parke, Davis reduced its dividend from \$1.45 in 1965 to \$1 in 1967 and to \$0.60 in 1970.

20. The record suggests a number of contributing factors to Parke, Davis' precipitous decline. One factor was problems with the company's principal antibiotic, Chloromycetin, a drug which had accounted for more than 20 percent of Parke, Davis' total sales as recently as 1967. [6] Chloromycetin's patent expired in October 1966, and it also received bad publicity as a result of certain fatal side effects. Subsequent declines in Chloromycetin sales volume and price adversely affected Parke, Davis' earnings. Parke, Davis' poor performance has also been attributed to management shortcomings (Tr. 2645), to outmoded marketing and poor coordination between marketing and R&D (Tr. 3572-74), and to a general non-aggressiveness in the marketplace. (Tr. 3025, 3675).

21. Whatever the cause of Parke, Davis' deterioration, by mid-1970, the Parke, Davis R&D effort had been significantly affected by the company's low profitability. Dr. Sadusk, who was in charge of Parke, Davis' research, testified that when he joined Parke, Davis in 1967 its R&D budget of approximately \$15 million was spread over six or seven drug categories, with the result that there was not enough money in any of them to be productive. In his view, Parke, Davis had also failed to appreciate the implications of the Kefauver-Harris Amendments and had an inadequate clinical investigation department. These problems appear to be reflected in the disappointing productivity of the Parke, Davis R&D effort — only two new chemical entities (NCE's) were developed between 1965 and 1972. Since Parke, Davis' low profits precluded increasing the R&D budget, the number of categories in which research was conducted was cut; and, in an effort to improve earnings, R&D money was shifted from research on new single entity drugs to developmental efforts on duplicate and combination products.

## THE ACQUISITION

22. During the first half of 1970, Parke, Davis' deterioration continued. The company's net earnings, excluding an extraordinary capital gain of \$1.4 million, fell to \$5.6 million in the first six months of 1970, compared to \$9.9 million for the first six months of 1969.

23. Following an internal review of Parke, Davis, Warner-Lambert, on July 19, 1970, proposed a tax-free exchange of all Parke, Davis' common stock for 5,400,000 shares of Warner-Lambert's common stock. It recited, among other things, that the combination of the two companies would permit both companies to compete more effectively from both a marketing and research standpoint, and that very material economies appeared available in the overseas markets. Subsequently, Warner-Lambert was advised that it [7] would have to increase its offer in order to be acceptable to Parke, Davis. Warner-Lambert thereupon increased the offer to 6,600,000 shares of Warner-Lambert common stock. Warner-Lambert was unaware at that time that there was a competing offer by the Revlon Company under which Parke, Davis would have become a wholly-owned subsidiary of a newly-named company, Revlon-Parke, Davis, Inc.

24. On July 30, the Parke, Davis Board of Directors voted unanimously to reject the Revlon proposal and to accept the Warner-Lambert one. The controlling consideration was that Warner-Lambert had a good reputation and an appreciation and knowledge of drug research and development, whereas Revlon, principally a cosmetic firm, lacked comparable standing and experience in the complex pharmaceutical field. Dr. Sadusk, Parke, Davis' R&D chief, testified that he considered it mandatory that any Parke, Davis merger should "be with a company which had an appreciation and knowledge of the ethics of drug development, [and] drug sales, and knowledge of research and development." (Tr. 2783).

25. The shareholders of the two companies approved the transaction at meetings held on October 2, 1970, and October 23, 1970, respectively. The transaction was completed on November 13, 1970.

## ISSUES TO BE DETERMINED IN THIS PROCEEDING

26. The Commission is called upon to determine whether the merger of Warner-Lambert and Parke, Davis violates Section 7 of the Clayton Act with respect to two principal markets — the drug manufacturing industry as a whole and its ethical segment — and twenty alleged drug product submarkets, to wit: thyroid preparations; anti-anginal drugs; cold remedies; oral decongestants; cough remedies; cough drops and lozenges; antihistamines; bronchial dilators; antacids;

irritant laxatives (ethical); emollient/protective dermatological preparations promoted ethically; prenatal vitamins; antibiotics for gram negative bacterial infections; ampicillin; anti-pseudomonas drugs; urinary antibacterials (non-sulfa); mouthwash; normal human serum albumin; immune serum globulin; and tetanus immune globulin.<sup>1</sup> There is [8] no issue as to "section of the country," respondent having admitted that all alleged markets and submarkets are nationwide in scope. (Answer ¶ 6.) Likewise, there is no issue between the parties as to "line of commerce" with respect to the two major markets and 13 of the alleged submarkets. As to all markets and submarkets, respondent denies that the merger will have the proscribed anti-competitive effect.

#### STIPULATION WITH REGARD TO INDUSTRY STATISTICS

27. The parties stipulated that Davee, Koehnlein and Keating (DKK) statistical data would "be used by both sides to establish the approximate dollar value of purchases of drugs and diagnostic materials, the breakdown of such purchases by product, by brand and by maker and the aggregate of all such purchases, direct or indirect, from each such maker during each of the years from 1957 through 1971, inclusive." (Stipulation Concerning Statistical Data, CC Phy. Ex. 2 at 1). They stipulated further that "such data shall be used to establish the approximate size of all product markets, both major markets and submarkets thereof, and the percentage market shares and ranks of each maker of products in such market (including Warner-Lambert and Parke, Davis)." (*Id.*). This provision was subject to exceptions permitting reliance on Nielsen data in the mouthwash and cough drop/lozenge submarkets, and on Nielsen data in combination with DKK data in the antacid submarket. Additionally, respondent reserved all objections to use of DKK data with reference to cough drops except to establish purchases by drug stores and hospitals, as distinguished from total or non-drug outlet purchases. The stipulation recited that while its purpose was "to place primary reliance on DKK statistics," it was not intended "to limit the taking of official notice of any U.S. Census data and the making of any proper use of such data \* \* \*." (*Id.* at 3). [9]

<sup>1</sup> Although the complaint alleged violations in fifty-five submarkets, only twenty remained at issue. Ten of the fifty-five pleaded submarkets were abandoned by complaint counsel during the course of the pre-hearing proceedings, as set forth in complaint counsel's Limitation of Proof dated March 8, 1973. In the Limitation of Proof, complaint counsel further disclaimed any intent to establish market definition or prove a violation in an addition twenty-two submarkets denoted as "Appendix B" submarkets. Subsequently, all proof with regard to the Appendix B submarkets was barred by ruling of the administrative law judge (Tr. 871). During the course of the hearing, complaint counsel abandoned three additional submarkets (Tr. 168-69, 2579), two of which were dropped in response to the Commission's Order of October 5, 1973, barring evidence of pre-NDA research "on the question of whether a firm should be considered a potential entrant into a market because of research activity."

THE DRUG MANUFACTURING AND ETHICAL DRUG LINES OF  
COMMERCE

28. The drug manufacturing line of commerce (sometimes referred to herein as the "all drug line") includes the manufacture and sale of all drugs, both ethical and proprietary. The ethical drug line of commerce embraces only ethical drugs. As noted above, respondent has admitted that both of these major lines are proper lines of commerce for Section 7 purposes. For purposes of this case, "drugs" are medicines, both pharmaceutical and biological, in dosage form intended for human use; "ethical drugs" are those for which a prescription is required or which, although sold over-the-counter without a prescription, are primarily promoted to the medical, pharmacy and allied professions; and "proprietary drugs" are those which are promoted primarily to the consuming public.

The ethical drug line accounts for more than 80 percent of industry sales in the all drug line, and virtually all of Parke, Davis' sales were and are in ethical drugs. For these reasons, the ethical drug line is the more significant of the two major lines of commerce being considered in this case.

## BARRIERS TO ENTRY

29. The record indicates three principal barriers to entry among various ethical drugs: The common use of brand name prescribing; patent barriers; and the high cost of research and development.

(a) *Brand name prescribing.* To the extent that brand name prescribing is utilized, a new entrant often finds it difficult to compete solely on the basis of price, quality, and service. This is because if a doctor writes a prescription by using a brand name or trade name, virtually every State requires by law or pharmacy board regulation that the dispensing pharmacist fill the prescription with the designated brand even though equivalent generic products may be available. Upwards of 75 percent of all prescriptions are written in brand name terms. Physicians are educated to the use of products by brand names by journal advertising, direct mail advertising, and by detailmen who visit them and leave promotional literature and samples. Even if a physician becomes aware of cheaper substitutes, it is common for many physicians to prescribe by brand name because of familiarity with that name or because he knows who makes it and he may feel more confident in the quality [10] of such product. As a result of this marketing system, drug companies with effective, large-scale promotional capabilities can establish brand names in the minds of physicians



and substantially exclude competing generic products or trademarked products sold by companies with more limited promotional capabilities.

(b) *Patents.* An inventor of a patented drug or manufacturing process is provided with a 17-year period for the exclusive use of such drug or process. This legal monopoly is an absolute barrier to competition, since no one else can sell the patented product or use the patented process without the permission of the inventor. One of the alternatives of competing with patented drugs — development of a competing therapeutic substitute — is available only to firms with substantial financial resources and research laboratories. Although an inventor of a patented drug can license others, such licenses are often not granted unless the patentee obtains a license on an important patented product or process. As a result, licenses are not exchanged except among the larger, established drug houses. Even after a patent expires, entry into the product line does not necessarily become easier since the patentee's brand name will have become established with doctors over the 17 years the patented drug is protected.

(c) *High Cost of Research and Development.* New products are the "life blood" of the drug industry, and research and development is a long, difficult, and complicated process. Hundreds or even thousands of compounds may be investigated of which only a handful will prove to be worthy of further trial. After a product is developed it must, in addition, undergo extensive and expensive clinical testing to determine safety and efficacy as required by the laws enforced by the Food and Drug Administration. A study by the Pharmaceutical Manufacturers Association found a ratio of research budget to sales of 11 to 11.5 percent, underscoring the substantiality of the costs of doing pharmaceutical research. This cost of ethical research represents a higher budgetary commitment than in almost any other industry. The Bureau of Census - National Science Foundation study of research and development computed an R&D to sales ratio for the pharmaceutical industry in 1970 of 6.5 percent while for all other industries, the study found an average ratio of only 3.8 percent. The drug industry ratio was the third highest of the 20 industries surveyed, exceeded only by electrical equipment and aircraft missiles.

30. Product differentiation is an important entry barrier among proprietary drugs. Through heavy advertising of brand names, major pharmaceutical manufacturers have established a competitive advantage in marketing. Public acceptance is greater when there is familiarity with a company name or a trademark. [11]

#### INDUSTRY CONCENTRATION AND MARKET SHARES

31. Set forth in Table I below are the market ranks and shares in

the ethical drug and all drug lines of commerce for all firms which ranked among the top eight in any of the years 1957, 1965 or 1969: [12]

TABLE I<sup>2</sup>

*ETHICAL*

	1957		1965		1969	
	Rank	% Share	Rank	% Share	Rank	Share
Lilly	1	8.54	1	6.57	1	7.37
American Cyanamid	2	6.99	7	4.34	12	2.89
American Home Products	3	6.88	2	5.82	3	6.31
Upjohn	4	6.66	5	5.24	7	4.17
Parke, Davis	5	5.96	10	4.04	11	2.90
Smith, Kline & French	6	5.74	3	5.62	8	4.17
Beechnut	7	4.94	9	4.11	9	3.66
Abbott	8	4.60	8	4.18	6	4.47
Merck & Co.	11	3.54	4	5.38	4	5.90
Roche	17	1.64	6	5.18	2	6.52
Bristol-Myers	*	*	21	1.66	5	5.10

*ALL DRUGS*

Lilly	1	7.38	2	5.67	2	5.97
American Home Products	2	7.02	1	6.11	1	6.63
American Cyanamid	3	6.07	7	3.74	16	2.34
Upjohn	4	5.75	5	4.66	9	3.48
Parke, Davis	5	5.15	11	3.57	15	2.42
Smith, Kline & French	6	4.96	3	5.39	6	3.92
Beechnut	7	4.27	9	3.74	11	3.17
Abbott	8	3.98	8	3.74	7	3.76
Merck & Co.	12	3.06	4	4.79	5	4.95
Roche	18	1.42	6	4.63	3	5.41
Bristol-Myers	20	1.14	15	2.18	4	5.25
Sterling	11	3.15	12	2.95	8	3.60

[13] 32. Based on stipulated DKK data, four-firm and eight-firm concentration in the ethical drug and all drug lines of commerce were as follows for the years 1957 through 1971:

TABLE II

Ethical Drugs (RX 1860)

All Drugs (RX 1861)

<sup>2</sup> Sources: Ranks - RX 1862 Revised A; % Share - RX 1863 Revised; Ranks - RX 1864 Revised A; % Share RX 1865 Revised.

	Findings of Facts and Conclusions of Law				87 F.T.C.
	<i>CR4</i>	<i>CR8</i>	<i>CR4</i>	<i>CR8</i>	
	1957	29.07	50.31	26.22	44.58
1958	27.82	49.17	25.43	43.78	
1959	26.95	48.19	24.76	43.01	
1960	25.52	46.86	23.24	41.31	
1961	26.00	45.79	23.44	40.43	
1962	25.35	44.14	23.38	39.77	
1963	24.66	43.54	23.04	39.54	
1964	23.81	42.34	22.46	38.95	
1965	23.39	42.33	21.96	38.73	
1966	24.35	42.75	22.74	39.23	
1967	25.22	43.64	22.97	40.35	
1968	25.44	43.75	22.58	38.93	
1969	26.10	44.01	23.26	39.49	
1970	26.29	44.43	23.80	41.38	
1971	26.56	43.71	23.87	40.65	

33. The size distribution of firms in both the ethical drug and all drug lines of commerce is characterized by uniformity rather than by domination by one or two large firms. This is illustrated by the Table below which depicts size distribution among the top four and top eight ethical drug firms.

TABLE III

## SIZE DISTRIBUTION OF TOP 8 ETHICAL DRUG FIRMS OF 1969

	<i>Share</i>	<i>% of CR4</i>	<i>% of CR8</i>	<i>% of (CR- C4)</i>
Lilly	7.37	23.24	16.75	
Roche	6.52	24.98	14.81	
AHP	6.31	24.18	14.34	
Merck	5.90	22.61	13.41	
CR4	26.10			
Bristol-Myers	5.10		11.59	23.48
Abbott	4.47		10.16	24.96
Upjohn	4.17		9.48	23.28
SKF	4.17		9.43	23.28
CR 8	44.01			

Source: RX 1824

[14] 34. The record demonstrates that Parke, Davis was among the top eight manufacturers of ethical drugs until it dropped to tenth in 1964 and never recovered its position. Warner-Lambert was never among the top eight until the merger. This is also true of both companies in the overall drug market. Consequently, counsel in support of the complaint rely principally upon stipulated DKK

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statistical data for the top 20 firms in both markets for the year 1969, the year prior to the merger. This data shows the following:

TABLE IV

Twenty Largest Suppliers of Ethical Drugs Purchased by U.S. Hospitals, Drug Stores, etc. in 1969 (CX 873)

	\$000,000	Ranks	%	App. rank as proprietary drug supplier
Eli Lilly & Co.	\$278.5	1	7.38	124
Hoffman-La Roche, Inc.	246.6	2	6.53	NA
American Home Products Corp.	238.6	3	6.32	2
Merck & Co., Inc.	223.0	4	5.91	24
-----				
<i>Warner-Lambert-Parke, Davis Combined</i> (Assuming merger in 69)	196.8	5	5.21	5
-----				
Bristol-Myers Co.	186.3	5	4.94	5
Abbott Labs.	169.7	6	4.50	43
Upjohn Co.	157.8	7	4.18	34
Smith, Kline & French Labs	157.7	8	4.18	10
Squibb Beech-Nut, Inc.	138.3	9	3.66	20
Pfizer, Inc.	126.7	10	3.36	11
<i>Parke, Davis &amp; Co.</i>	109.5	11	2.90	44
American Cyanamid Co.	109.4	12	2.90	83
G.D. Searle & Co.	94.6	13	2.51	909
Schering Corp.	89.3	14	2.37	23
<i>Warner-Lambert Pharmaceutical Co.</i>	87.3	15	2.31	4
Johnson & Johnson	86.9	16	2.30	9
Sterling Drug, Inc.	85.5	17	2.26	1
A.H. Robins & Co., Inc.	79.3	18	2.10	22
Sandoz-Wander, Inc.	76.6	19	2.03	NA
Ciba	75.3	20	2.00	27
All other suppliers	956.8		25.36	
Total purchases of drugs --- U. S. Hospitals, Drug Stores, etc.	3,773.7		100.00	

[15] TABLE V

Twenty Largest Suppliers of all Drugs Purchased by U.S. Hospitals, Drug Stores, etc., in 1969 (CX 877)

	\$000,000	Rank	%
American Home Products Corp.	\$309.7	1	6.63
Eli Lilly & Co.	278.8	2	5.96
-----			
Warner-Lambert - Parke, Davis Combined (Assuming merger in 1969)	256.4	3	5.49
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	Findings of Facts and Conclusions of Law		87 F.T.C.
Hoffman-La Roche, Inc.	252.6	3	5.40
Bristol-Myers Co.	245.7	4	5.26
Merck & Co., Inc.	231.4	5	4.95
Smith-Kline & French Labs.	182.7	6	3.91
Abbott Labs.	176.3	7	3.77
Sterling Drug, Inc.	168.4	8	3.60
Upjohn Co.	162.6	9	3.48
Pfizer, Inc.	150.6	10	3.22
Squibb Beech-Nut, Inc.	148.0	11	3.17
Warner-Lambert Pharmaceutical Co.	143.5	12	3.07
Johnson & Johnson	118.2	13	2.53
Parke, Davis & Co.	112.9	14	2.42
American Cyanamid Co.	110.1	15	2.36
Richardson-Merrell Inc.	108.6	16	2.32
Schering Corp.	97.8	17	2.09
G.D. Searle & Co.	94.6	18	2.02
A.H. Robins & Co., Inc.	87.9	19	1.88
Ciba	81.8	20	1.75
All other suppliers	1,411.8	—	30.21
Total purchases of drugs - U.S. Hospitals, Drug Stores, etc.	4,674.0	—	100.00

[16] 35. As indicated in the above tables, in the 1969 *ethical drug* manufacturing industry, where Warner-Lambert ranked 15th with 2.31 percent and Parke, Davis ranked 11th with 2.90 percent of \$3.774 billion purchases, the acquisition *pro forma* raised Warner-Lambert's market share to 5.21 percent. Based on the same industry source, the merged firm's actual post-merger shares in 1970 and 1971 were 5.05 percent and 4.81 percent, respectively (RX 1826, 1828).

36. As indicated in the above tables, in the 1969 *overall drug* manufacturing industry, where Warner-Lambert ranked 12th with 3.07 percent and Parke, Davis ranked 14th with 2.42 percent of \$4.674 billion purchases, the acquisition *pro forma* raised Warner-Lambert's market share to 5.49 percent of sales. Based on the same industry source, the merged firm's actual post-merger shares in 1970 and 1971 were 5.47 percent and 5.27 percent respectively (RX 1856, 1858).

37. Table II, *supra*, shows that four-firm and eight-firm concentration ratios (CR's) in the major markets were virtually unchanged after the 1970 merger. Thus, the all-drugs CR4 went from 23.26 percent in 1969 to 23.87 percent in 1971, while CR8 in the same market went from 39.49 percent to 40.65 percent. (Adding the merging firms' 1969 market shares to calculate the merger's *pro forma* effect on concentration, there was less than a 2 percentage point increase CR8 in the overall drug industry.) In ethical drugs, CR4 rose from 26.10 percent in 1969 to 26.56 percent in 1971, while CR8 declined from 44.01 percent to 43.71 percent, less than what it was before the merger. (The merger's *pro*

*forma* effect on concentration was only about a one percentage point increase in CR8.)

38. The Commission finds that the firms' market shares in the ethical drug and overall drug markets are too small and had too insignificant an effect on concentration to create a presumption of illegality in either market.

39. Furthermore, the merger did not accompany any clear trend or movement toward concentration in these markets. This is indicated not only by Table II, *supra*, which is based on the DKK industry statistics, but is also borne out by available Census concentration ratios. The drug industry embraces two four-digit Census categories, 2834, Pharmaceutical Preparations, and 2831, Biological Products. The four-firm and eight-firm concentration ratios for these two categories up to the time of the merger have been: [17]

TABLE VI

	CONCENTRATION IN SIC 2834 <i>(Pharmaceutical Preparations)</i>		CONCENTRATION IN SIC 2831 <i>(Biological Products)</i>	
	<i>CR4</i>	<i>CR8</i>	<i>CR4</i>	<i>CR8</i>
1958	27	45	44	59
1963	22	38	36	57
1966	24	41	46	72
1967	24	40	39	63
1970	26	43	37	59

(CX 727)

Trends in the four-firm and eight-firm concentration ratios are generally regarded as having more significance than 20-firm concentration ratios in measuring competitive structure. Twenty-firm concentration figures also, however, fail to show a decisive trend toward concentration:

TABLE VII

(DKK Data)

	<i>Overall Drugs</i> <i>CR20</i>	<i>Ethical Drugs</i> <i>CR20</i>
1957	70.78	77.81
1960	69.69	75.47
1963	69.78	73.12
1966	68.94	73.86
1969	69.93	74.62

(RX 1863 Revised, 1865 Revised)

TABLE VIII  
(Census Data)

	CONCENTRATION IN SIC 2834 (Pharmaceutical Preparations) CR20	CONCENTRATION IN SIC 2831 (Biological Products) CR20
1958	73	84
1963	72	86
1967	73	86

(CX 727)

[18] 40. Although the existence of high entry barriers is a factor in weighing the loss of Parke, Davis as an independent firm in the market, other factors greatly minimize the horizontal effects of the merger in the overall markets. These factors include the lack of direct competition between Warner-Lambert and Parke, Davis in many individual end-use submarkets. The two companies' combined sales in the submarkets where we find each substantially competed with the other would amount to less than .5 percent of total industry sales in both the ethical and the overall drug lines of commerce. Another factor tending to reduce the competitive significance of the merger is the rapid decline in the drug industry and ethical segment experienced by Parke, Davis in recent years.<sup>3</sup> Warner-Lambert has never been among the leading ethical drug firms. It ranked 15th in 1957 and still 15th in 1969.

41. The Commission finds there has been no showing that competition may be substantially lessened in the overall drug industry and ethical drugs segment as a result of the acquisition.

#### INTRODUCTION TO FINDINGS ON ALLEGED DRUG PRODUCTS SUBMARKETS

Complaint counsel allege a violation of Section 7 in each of 20 alleged product submarkets. These submarkets are defined in terms of therapeutic end-use and correspond approximately to seven-digit Standard Industrial Classification (SIC) categories. Respondent has admitted that 13 of the submarkets are valid lines of commerce,<sup>4</sup> and

<sup>3</sup> As previously noted (Finding 17), in 1950, Parke, Davis ranked second in the drug industry. Ten years later, in 1960, Parke, Davis was still an industry leader, ranking third in the ethical drug line with 6.02 percent of sales (RX 1806), and fourth in the all drug line with 5.08 percent of sales (RX 1836). By 1969, Parke, Davis had dropped to 11th position in ethical drugs and 15th in the all drug line, with a market share in each line well below 3 percent. In 1971, the year after the merger, the Warner-Lambert/Parke, Davis combined ethical drug share was 4.81 percent (RX 1863 Revised) which is less than Parke, Davis alone accounted for ten years earlier (*id.*).

<sup>4</sup> The 13 admitted submarkets are cough drops and lozenges, cold remedies, oral decongestants, antihistamines, antacids, emollient/protective dermatological preparations promoted ethically, prenatal vitamins, ampicillin, urinary anti-bacterials (non-sulfa), mouthwash, normal serum albumin, immune serum globulin, and tetanus immune globulin.

(Continued)

both parties agree that the Nation as a whole is the relevant geographic market for all asserted product markets.

42. Complaint counsel contend that the merger has eliminated both actual (what in the complaint is alleged as "substantial existing (SE)") and potential ("PE") competition between Warner-Lambert and Parke, Davis.<sup>5</sup> The complaint itself charged that the merger would eliminate SE competition in five therapeutic submarkets. The remaining therapeutic submarkets involved contentions that Warner-Lambert or Parke, Davis was eliminated as a significant potential competitor because it was contemplating entry or already had a toehold position in a market where the other was strong. Complaint counsel, after the hearing, increased the number of alleged SE submarkets. They are now proposing eight SE submarkets: thyroid preparations, cough remedies, cold remedies, cough drops and lozenges, bronchial dilators, irritant laxatives (ethical), emollient/protective dermatological preparations promoted ethically, and anti-anginal drugs. We will deal first with the contentions relating to the eight alleged SE submarkets and then take up the remaining submarkets. [20]

#### A. THYROID PREPARATIONS

43. "Hypothyroidism" is the condition resulting from undersecretion by the thyroid gland of thyroid hormone, a substance having as its principal function the regulation of metabolic processes and rates within the body. Symptoms of hypothyroidism include general loss of energy, greater periods of sleep, slower response, preference for warm environment, weight gain, and slower pulse rate. The standard treatment for hypothyroidism is the administration of thyroid hormone.

#### *Natural Thyroid Therapy*

44. The two principal active chemical components of natural thyroid hormone are thyroxine (T-4) and liothyronine (T-3), both of which contain large proportions of iodine. While both T-3 and T-4 act to increase body metabolism, they differ in that T-3 is both more potent and more rapid-acting. Natural thyroid therapy dates back to the turn of the century but thyroid did not become a U.S. Pharmacopoeia ("USP") product until the late 1920's or early 1930's. To meet USP

The disputed submarkets are thyroid preparations, anti-anginal drugs, cough remedies, bronchial dilators, irritant laxatives (ethical), antibiotics useful against gram-negative bacilli, and anti-pseudomonas drugs.

<sup>5</sup> Complaint counsel have abandoned the distinction made in the complaint between the PE and the existing, imminent, or recent ("EIR") classifications insofar as "imminent or recent" competition is allegedly involved. Insofar as "existing" competition was embraced within the EIR classification, it is now denominated "toehold" competition.



standards natural thyroid must be cleaned, de-fatted and desiccated (dried). It must also contain no less than 0.17 percent nor more than 0.23 percent iodine, which, as noted above, is an index of the active ingredient of a thyroid hormone. In the natural state the T-4 and T-3 components of thyroid hormone are not found separately but only as part of the total thyroid complex.

45. At the time of this merger Parke, Davis had long been marketing two desiccated natural thyroid products: "thyroid USP" and a "thyroid strong," which is 50 percent again as potent as thyroid USP. Since 1940 Warner-Lambert had also been marketing a natural product under the trade name "Proloid." "Proloid" is called "thyroglobulin" rather than "thyroid USP" but it is a desiccated thyroid which meets USP standards and differs from thyroid USP in that it has been further washed and cleaned to remove certain inert materials.

#### *Synthetic Thyroid Therapy*

46. Thyroid preparations have also been made by chemical synthesis for about 20 years. The earliest synthetics were either T-4 alone or T-3 alone. In late 1969 Warner-Lambert brought out the first synthetic combination of T-4 and T-3, [21] known generically as liotrix, under the brand name Euthroid. By 1970 synthetic thyroid preparations accounted for 49.4 percent of the dollar value of all thyroid purchases by U.S. hospitals and drug stores (up from 46.1 percent in 1969), leaving natural thyroid preparations with 50.6 percent of the total value. In view, however, of much higher prices generally charged for synthetics<sup>6</sup>, it can be inferred that considerably less than half of all thyroid tablets purchased in 1970 were synthetic. According to one witness, most thyroid patients are still on natural thyroid therapy (Tr. 641-643).

47. Parke, Davis markets only unbranded thyroid. Warner-Lambert markets only branded thyroid: The nonsynthetic, purified product Proloid, and the synthetic T-4/T-3 combination, Euthroid. Complaint counsel urge that all thyroid preparations, including both branded and unbranded products, comprise a single line of commerce for Section 7 purposes. Respondent disputes this, contending that unbranded and branded thyroid preparations each compete only in separate markets. However, as indicated below, we find that the manufacture and sale of all thyroid preparations are a proper line of commerce for purposes of this case.

<sup>6</sup> The least expensive thyroid products are the USP preparations. The price of Proloid is approximately twice that of the USP thyroid, while the synthetic products are approximately twice that of Proloid. The retail price of a USP thyroid tablet is approximately one to two cents.

## Functional Interchangeability

48. There is almost complete therapeutic substitutability between all kinds of thyroid preparations, natural and synthetic, for treatment of hypothyroidism (Tr. 634, 646, 876, 1820, 1834, 1837-39; CX 3664). The exceptions to this rule are minor. One requires recourse to T-3 only in certain situations. The T-3 component of thyroid hormone is more potent and acts more quickly (and by the same token has a shorter duration of action) than the T-4 component or any natural or synthetic combination of T-4 and T-3 (Tr. 634-635). For that reason the use of T-3 alone may be preferred for quick diagnoses or in case of therapeutic emergencies. Another exception is the occasional need for injectable administration to unconscious patients, available only in the case of synthetic thyroid preparations (Tr. 639; Tr. 1835). Otherwise the indications for use of all thyroid preparations, natural and synthetic alike, are substantially identical.

[22] 49. The only advantage of synthetic over natural thyroid lies not in any superior therapeutic qualities but rather in its known, fixed content which permits better control over the chemical purity of the material and thus facilitates blood testing in aid of diagnosis and/or therapy. The variation inherent in different individual animal thyroid glands, for example, may yield T-4/T-3 ratios ranging from 2-1 to 5-1. By contrast, the T-4/T-3 ratio in synthetic thyroid may be standardized during manufacture. In chemical assays synthetic hormones with known, fixed T-4/T-3 content tend to give more reproducible chemical analysis results which vary less with the material than in the case of natural hormones. Since such blood tests perform a useful function in aid of the attending physician's diagnosis and therapy, the somewhat greater accuracy of tests performed with synthetic thyroid may be considered a quality advantage. The quality advantage, however, is only a "rather minor" one of patient management, yielding no advantage in clinical results, according to complaint counsel's pharmacological expert, Dr. Frank Standaert. (Tr. 640, 641, 642). This is because in the last analysis chemical assays are merely aids to a physician's judgment from pragmatic, clinical testing which must always prevail (Standaert Tr. 642; see also Modell Tr. 3368), even if it seems contradictory of the blood test results. Dr. Mark Lund, a former Warner-Chilcott thyroid research director, testified that, while he would expect lab results with synthetic combinations to be more predictable than with natural products because of greater consistency, he was not sure whether these variations would be "clinically important" (Tr. 1845). No witness questioned Dr. Lund's skepticism of Dr. Standaert's ultimate conclusion that the generally lesser variation

in T-4/T-3 ratio characteristic of synthetic thyroid "has no real practical effect on the way you manage the patient" because "you can achieve the same goal with all of them. You regulate your dose of all of them [natural and synthetic alike] to achieve this goal the same way" (Tr. 641-42).

The Commission finds that while the known, fixed content of synthetic thyroid to some extent facilitates chemical assays in aid of clinical judgment, this is at most a minor quality advantage against which must be weighed the long and satisfactory experience which the medical profession has had with natural thyroid and does not require subdivision of thyroid sales for purposes of antitrust analysis. [23]

#### Buying Practices

50. Thyroid preparations are dispensed only on a physician's prescription. The fact that the prescribing physician makes the choice as to the thyroid preparation means that price competition between thyroid products manufactured by different companies will be a factor for a pharmacist or patient only if the physician omits to specify a particular brand. Although, as respondent contends, most physicians may tend to be fixed in their prescribing habits in this as in other areas of treatment (some preferring a brand natural thyroid, some preferring a branded synthetic thyroid), physicians are still free to take price into consideration and some, even if a minority, are presumably conscious of price differences between unbranded and branded since a substantial number prescribe the former despite promotions of the latter. Furthermore, we cannot assume that physicians are so fixed in their prescribing habits that a substantial increase in the existing price differential between branded and nonbranded thyroids would never cause a shift toward more prescriptions of lower priced thyroid. Warner-Lambert's own advertisement (CX 910) assumes that prescribing habits are not immutable, as it indicates how patients may be switched to Euthroid from other natural or synthetic thyroid preparations, whether branded or unbranded. We therefore reject respondent's contention that branded and unbranded thyroid preparations must be placed in separate product markets.

#### Market Structure and Market Shares

51. Purchases of all thyroid preparations by U.S. drug stores and hospitals, which by stipulation of the parties, are to be treated as a reasonable approximation of the entire U.S. market for thyroid preparations are set forth in the following table. [24]

TABLE IX

*Thyroid Preparations*  
1969 and 1970 U.S. Purchases by Drug Stores and Hospitals.

	1969			1970		
	(\$000)	%	Rank	(\$000)	%	Rank
Total	\$17,935	100.0		\$19,581	100.0	
Armour (Greyhound Corp.)	3,386	18.9	4	4,490	22.9	1
Flint (Baxter Labs Inc.)	3,735	20.8	1	4,211	21.5	2
Warner-Lambert	3,647	20.3	2	4,079	20.8	3
SKF (Smith Kline & French Labs)	3,560	19.9	3	3,375	17.2	4
Parke, Davis	837	4.7	5	892	4.6	5
Lilly (Eli Lilly & Co., Inc.)	279	1.6	6	322	1.6	6
McKesson (Formost-McKesson)	150	0.8	7	115	0.6	7
Rexall (Dart Industries, Inc.)	23	0.1		39	0.2	8
McNeil (Johnson & Johnson)	29	0.2	8	30	0.2	
Four largest	14,328	79.9		16,155	82.4	
Eight largest	15,623	87.2		17,523	89.4	
24 other firms	142	0.7		138	0.8	
All other suppliers	2,170	12.1		1,920	9.8	

(Source: CX 902).

[25] 52. As indicated in Table IX, the top four suppliers, including Warner-Lambert, accounted for about 80 percent of all purchases in 1969 and 82 percent in 1970, while the top eight suppliers, including both Warner-Lambert and Parke, Davis, accounted for 87 percent of all purchases in 1969 and about 89 percent in 1970. Thus, the thyroid preparations manufacturing market is highly concentrated.

#### Competitive Injury

53. On the basis of the 1970 market shares shown in Table IX, the acquisition of fifth-ranked Parke, Davis by third-ranked Warner-Lambert made the latter the first-ranked firm in the market and increased four-firm concentration from 82.4 percent to 87.0 percent. The market share for Parke, Davis (4.6 percent) understates the importance of that company's position in the market since Table IX is based on dollar sales. In view of the fact that Parke, Davis' USP thyroid sells for one-half to one-fourth the price of branded thyroid preparations, Parke, Davis has a higher market share based on unit sales. (Three of the four leading companies, Flint, Warner-Lambert, and SKF, sell *only* branded thyroids. The fourth, Armour, sells both

branded and unbranded thyroid preparations. Parke, Davis, Lilly, and Rexall sell only unbranded thyroid products).

53a. The Commission finds that such an increase of concentration in a market already concentrated substantially lessens competition within the meaning of Section 7. The high degree of concentration, substantially augmented by this merger, outweighs any countervailing considerations based on the fact that Warner-Lambert's thyroid products are sold at a different price level than Parke, Davis' and that entry barriers in this submarket may not be as high as other therapeutic submarkets. The presence of an independently priced Parke, Davis' product is necessary to assure physicians the choice of prescribing a lower-priced product. [26]

#### B. COUGH REMEDIES

54. A cough can be treated either by eliminating the underlying cause — removing a foreign particle or curing an infection — or by treating the cough itself symptomatically. Symptomatic treatment can be accomplished either by relieving the irritation locally or by suppressing the cough reflex in the brain. Materials which act locally to accomplish symptomatic cough relief include demulcents, local anesthetics and expectorants. Demulcents are soothing syrupy or sugary substances which soothe the irritated surface. Local anesthetics include substances such as chloroform, hexylresorcinol and benzocaine. Expectorants are used to induce secretions in the lung portion of the respiratory tract thinner so it can be coughed out. Expectorants include simple salts and certain herbal substances.

55. Materials which act on the brain, or central nervous system, to inhibit the cough reflex are known as antitussives. The most widely used antitussives are codeine and dextromethorphan. Codeine has several undesirable side effects, including constipation, dizziness, confusion and, in some instances, addiction. As a result, it is regulated as a "Class V" narcotic, requiring that all purchasers thereof register with a pharmacist. Dextromethorphan is as effective as codeine but has fewer side effects; in particular, it has a markedly smaller tendency toward abuse and is, therefore, not regulated in the same way as codeine. For these reasons, there is now a tendency, in cough preparations, to use dextromethorphan in preference to codeine. Dextromethorphan can be and is incorporated in cough drops, lozenges, syrups, and tablets and its mechanism is the same regardless of product form.

56. There are essentially three physical forms in which cough remedies are manufactured: (1) liquid syrups designed to be swallowed, (2) tablets and capsules designed to be swallowed, and (3) cough

drops and lozenges, designed to be dissolved in the mouth. The liquid preparations can contain antitussives, expectorants, demulcents (usually the syrupy base) or any combination of these three. The tablets and capsules can contain antitussives and/or expectorants. Since the tablets and capsules are designed to be swallowed and not dissolved, there would be no point in incorporating a demulcent therein. Cough drops and lozenges always contain a demulcent base, which may be accompanied by antiseptics, local anesthetics, dextromethorphan, or any combination of these three.

[27] 57. Cough remedies are marketed as either proprietary or ethical products. Of the ethical products, some are available by prescription only, while others can be purchased by consumers "over the counter" (the so-called "ethical OTC" drugs).

#### Parke, Davis' Cough Remedy Products

58. Parke, Davis' position in the prescription cough medication field is due primarily to Benylin Expectorant and Ambenyl Expectorant. *Benylin Expectorant* is a syrup containing the antihistamine Benadryl, the menthol and alcohol. Benylin had 1970 factory sales of \$3,600,000. *Ambenyl Expectorant* is also a syrup, and contains two antihistamines (Benadryl and Ambodryl), expectorants, and the antitussive codeine. Ambenyl had 1970 factory sales of \$1,500,000.

59. Parke, Davis also markets several generic OTC products, including *Terpin Hydrate Elixir NF* (1970 sales: \$42,000), *Terpin Hydrate and Codeine Elixir NF* (1970 sales: \$514,000), *Mentholated Expectorant Syrup* (1970 sales: \$11,000), and *White Pine and Cherry Expectorant Syrup with Tar* (1970 sales: \$13,000). Three other generic OTC's — *Terpin Hydrate and Codeine Elixir P.D. & Co.*, *Expectorant Mixture Solution* and *White Pine Compound Syrup* — with total 1970 sales of \$95,000, were discontinued in July and August of 1970.

Parke, Davis has also marketed three branded ethical cough syrups, *Cosanyl*, *Cosanyl-DM* and *Cosadein*. On September 1, 1970, a new product, *Cosanyl-DM Cough Syrup (Improved Formula)* was marketed and subsequently the old formulation of *Cosanyl-DM*, as well as *Cosanyl*, was discontinued on January 13, 1971. The record does not show whether the *Cosadein* formulation was discontinued or whether similar "improved" formulations of *Cosanyl* and *Cosadein* were ever introduced. Factory sales in 1970 of the three old formulations were:

Cosanyl	\$840,000
Cosanyl-DM	\$100,000
Cosadein	\$195,000

Cosanyl-DM Cough Syrup (Improved Formula) appears to have annual factory sales of approximately \$214,000.

61. Parke, Davis *Medicated Throat Discs*, is a compressed lozenge composed of chloroform and various essential oils. It had 1969 factory sales of \$1,506,000. [28]

#### Warner-Lambert's Cough Remedy Products

62. Warner Lambert markets no ethical OTC cough preparations; and with the exception of some proprietary cough syrups (factory sales totaling \$106,000 in 1970), and a prescription cough/cold preparation, *Nilcol* (factory sales in 1970 — \$700,000) Warner-Lambert's cough preparations are proprietary cough drops and lozenges, consisting of; (a) *Smith Brothers Cough Drops*. Factory sales of Smith Brothers Cough Drops was \$2,260,000 in 1970. (b) *Hall's Mentho-Lyptus Cough Tablets* contain menthol and eucalyptus oil as active ingredients. In 1970, Hall's had factory sales of \$6,000,000. (c) *Listerine Throat Lozenges* contains the topical anesthetic hexylresorcinol as its active ingredient. It is promoted for relief of sore throat pain, but respondent agrees that it is also a cough remedy product. Sales of *Listerine Throat Lozenges* were \$7,200,000 in 1970. (d) The only antitussive-containing cough drop or lozenge marketed by Warner-Lambert is *Listerine Cough Control Lozenges*, containing the antitussive dextromethorphan and the local anesthetic benzocaine.

#### Market Definition

63. Complaint counsel contend that all products useful against coughs constitute a market. Respondent takes the position that all cough remedies cannot be placed in one market, that cough drops and lozenges constitute a market separate from cough syrups. The record demonstrates, however, that all cough remedy preparations have the same end use, *i.e.* symptomatic treatment of cough. This is confirmed by a comparison of the advertising for respondent's cough syrups — “ \* \* \* gives prompt relief from coughs \* \* \*.” (CX 1497) with that for its cough drops, *e.g.* Hall's Mentholiptus Cough Drops “For temporary relief of coughs \* \* \*.” (CX 1507) — and for its cough lozenges, *e.g.* Parke, Davis' Medicated Throat Discs — “ Effective for the quick relief of coughs \* \* \*.” Both prescription and non-prescription cough preparations have this same end use; *i.e.* the symptomatic treatment of relief of coughs. For example, Warner-Lambert's prescription product *Nilcol* is indicated for “\* \* \* symptomatic relief of congestion and cough in upper respiratory disorders” (CX 1495); Parke, Davis non-prescription product *Cosanyl* is indicated for “relief of irritating cough

\* \* \*." (CX 1539). Other than the situation where a product has to be dispensed on prescription, consumers purchase cough preparation on the recommendation of physicians, [29] even though the product does not require a prescription, on the recommendation of pharmacists, and by their own choice (Tr. 755; 1689-1691). Market surveys made for Warner-Lambert show that consumers use drops, lozenges, tablets and capsules as well as syrups, variously, to treat coughs. (CX 1486-1487). The only exception is where a physician may want to prescribe larger amounts of codeine or an antihistamine or decongestant than is found in an ethical OTC or proprietary product. Even here there is competitive substitutability. To the extent a consumer treats himself with a cheaper proprietary or over-the-counter remedy when a physician might have prescribed an RX syrup, and vice versa, demand is transferred from one type of product to the other. Warner-Lambert itself test-markets cough drops against syrups indicating that its marketing department recognizes that these products are in a common product market. Considering all the circumstances, we find that all cough preparations constitute an appropriate line of commerce even though "cough drops and lozenges" and "cough syrups" constitute separate submarkets (Finding 68, *infra*).

#### Market Structure

64. Data in the record shows the following estimate of market size (census data) and shares:

TABLE X  
Cough Remedies

	1968		1969	
	\$ (000)	%	\$ (000)	%
Universe (Census)	192,442	100	207,892	100
Warner-Lambert	6,843*	3.6	9,239*	4.4
Parke, Davis	7,874	4.1	8,771	4.2
Combined	\$14,717	7.6	\$18,043	8.7

Source (CX 1461-1462)

[30] The combined firms shared 7.6 percent of this \$200 million nationwide market in 1968 and a percent more in 1969, not including Warner Lambert's \$5.2 million sales of Hall's cough drops. DKK's 1969 survey of hospitals and drug stores gave Parke, Davis 3rd rank with 6.7 percent of the market and Warner-Lambert 10th rank with 2.9 percent of the market (CX 3457).

\* Excludes Halls Mentho-Lyptus sales, which are imported from England and are, therefore, not included in SIC measure of domestic production.



65. The market is concentrated. Although census figures are not available with which to construct concentration ratios exactly, in the hospital-drug store market sampled by DKK the four largest firms had 45 percent in 1969 and the eight largest 63 percent (CX 3457). The acquisition raised four-firm and eight-firm concentration nearly 3 percent.

66. There are also substantial barriers to effective competition at the marketing distribution level. In addition to the barriers concerning the generation of physician prescription by brand name and insuring availability of the product in retail outlets, there are the marketing and merchandising barriers necessary to successful creation and fulfillment of a consumer demand for proprietary products.

67. Although nearly all of Warner-Lambert's cough remedy sales are of cough drops and lozenges, and over 83 percent of Parke, Davis' sales are of cough syrups, the differing characteristics of these two types of products (drops and lozenges versus syrups) are not so extreme as to eliminate the inference of substantial anticompetitive effects indicated by the market shares held by each firm in this market. In so finding, we have taken into consideration the following additional facts.

(a). Prior to its acquisition by Warner-Lambert, Parke, Davis was actively seeking to improve its position in this market both by an increased marketing and promotional effort for existing products, and by new product development. In December 1968, Parke, Davis commissioned a marketing study to determine the adequacy of its promotional program for Benylin Expectorant. (CX 1564-1569). In 1969, Parke, Davis requested FDA approval to sell Benylin Expectorant over-the-counter (CX 492), anticipating it would achieve [31] an OTC volume of \$1.8 million in six months (CX 587). (Benylin is now sold as an over-the-counter cough syrup.) To achieve a "substantial increase" in total volume by virtue of OTC sales, (CX 1577), Parke, Davis planned to supplement existing medical advertising with an additional \$125,000 for medical journals, \$65,000 for direct mail and \$225,000 for retail promotion of Benylin OTC (CX 494). In February and March of 1970, Parke, Davis' ability to develop and market cough preparations is attested to by its own marketing personnel, *e.g.*, the 1970 marketing plan stated:

Opportunities are available to improve our Expectorant market penetration. The introduction of two proposed new Benylin formulations in 1971 could produce \$1,000,000 or more in a relatively short period of time (CX 493).

(b). Warner-Lambert has had a substantial commitment to basic

and applied research with the objective of developing "new drugs and/or drug combinations superior to existing marketed products used in the cough-cold area in respect to potency, efficacy, onset and duration of action;" in 1969 expenditures totalled \$281,400, included in which are grants and fellowships to "experts and centers prominent in respiratory research" (CX 1512). Similar expenditures in 1970 for proprietary drugs in the area of respiratory research amounted to \$230,000 (CX 1518). This research has included studies of expectorants because of Warner-Lambert's "potential interest" (CX 1513), and the evaluation of bronchodilators and antihistamines for their antitussive activity (CX 1512, CX 1519). Warner-Lambert also expends substantial sums on improving existing products (CX 1519-1520, CX 1516, CX 1511). As the result of a development project which cost over \$50,000 in the first half of 1970 alone (CX 1516), Warner Lambert has also introduced a new product: Listerine Cough Control Lozenges.

[32] Although, as noted, Warner-Lambert's sales are heavily weighted toward cough drops and lozenges, it has been developing syrup products. In addition to Nilcol, introduced in 1970, it has test marketed a Silenex brand cough syrup and has under development Smith Brothers Cough Syrup. Its total syrup sales (including Nilcol) have been expanded several fold between 1968 and 1970 (CX 1462, RX 1797).

(c). Prior to the acquisition, Warner-Lambert was increasing its market share. Table X *supra*.

In conclusion, we find that the merger substantially lessened competition in the cough remedies. [33]

#### C. COUGH DROPS AND LOZENGES

68. Cough drops and lozenges have particular characteristics and uses which set them apart as a separate submarket of cough remedies in general. They are more portable than liquid cough remedies and are often used for coughs of less severity. In addition, there are some differences between cough drops and cough lozenges that indicate that competition *intra* drops and *intra* lozenges is greater than *between* drops and lozenges. They are often displayed at different points in the retail store. Cough drops are usually located at the candy counter, while lozenges are generally found on the drug counter. Cough drops are generally priced below<sup>7</sup> \$.40, while lozenges are priced at \$.70 up to two dollars. Nevertheless, respondent does not dispute that cough drops and lozenges together constitute a relevant "line of commerce."

69. Respondent further agrees that Warner-Lambert was among

<sup>7</sup> Parke, Davis' lozenge product, Medicated Throat Discs, is an exception since it retails at a price around forty cents.

the leading firms in the cough drop and lozenge market with about a 27 percent market share, and that Parke, Davis' share was almost 3 percent. Warner-Lambert markets two cough drops — Smith Brothers Cough Drops, Hall's Mentho-Lyptus Cough Tablets — and two cough lozenges — Listerine Throat Lozenges and Listerine Cough Control Lozenges. Parke, Davis' position in this market is due entirely to Medicated Throat Discs. Respondent argues that Parke, Davis' position should be disregarded because its only product in this market was "outmoded" in 1970. The record shows that instead of being an "outmoded" product, Parke, Davis' Medicated Throat Discs have been popular for many years. In the two years prior to the merger, Medicated Throat Discs increased in sales from \$1.4 to \$1.5 million and Parke, Davis officials anticipated a further increase in both dollar and unit sales in 1970 (CX 1574). Although Medicated Throat Discs were not distributed to food stores, it was a successful over-the-counter product in drug stores as witnessed by a Parke, Davis study showing that "one out of every four throat lozenges sold in drug stores in 1968 was an MTD [Medicated Throat Disc]" (CX 1573). [34]

#### Market Size and Structure

70. Total U.S. shipments of cough lozenges are listed by Census at \$22.3 million in 1968 and \$20.6 million in 1969. From company figures, Warner-Lambert had sales of \$4.4 million in 1968 or 19.9 percent of all cough lozenges, and sales of \$6.7 million in 1969 or 32.6 percent of all cough lozenges. Parke, Davis had sales of \$1.4 million in 1968 or 6.4 percent of all cough lozenges, and sales of \$1.5 million in 1969 or 7.3 percent of all cough lozenges. This acquisition, therefore, results in a combined share of cough lozenges of 26.3 percent in 1968 and 39.9 percent in 1969.

While Census lists lozenges separately, it does not break out cough drops as a separate category. Nevertheless the parties have stipulated that market survey data prepared by A. C. Nielsen Co. on cough drops, are sufficiently reliable and accurate to establish total and company sales of cough drops (Tr. 1454). Total U.S. sales of cough drops were \$31.0 million in 1969 and Warner-Lambert had a volume of \$7.1 million or 22.9 percent of all cough drops sold in 1969. Warner-Lambert increased this share to 25.0 percent in 1970. Combining the two sets of data, (Census and Nielsen), Warner-Lambert's share of the lozenges-and-drops market in 1969 would amount to 26.8 percent and Parke, Davis' share would be 2.9 percent.

71. The market for cough drops and lozenges is highly concentrated. In cough drops, according to Nielsen, three firms — Richardson-Merrell, Warner-Lambert and Ludens had 84.4 percent in 1969 and 85.1

percent in 1970 (CX 1463). In the DKK category "Throat Preparations," which is the one containing Parke, Davis and Warner-Lambert cough lozenge products, the four largest firms had 85.2 percent and the eight largest 96.2 percent in 1969 (CX 3456). In this connection, it is noted that the total projected by DKK for its category "Throat Preps" — \$19.3 million in 1969 (CX 3456) — closely correlates with Census figures for cough lozenges: \$20.6 million in 1969 (CX 1464). Concentration ratios are available for purchases by the hospital-drug store segment of the market, and show that the four largest firms had 76.2 percent of combined cough drops and lozenges in hospital/drug store, (CX 3459). Considering the high concentration shown by DKK for "Throat Preparations" (*i.e.*, lozenges) separately (CX 3456) and for drops and lozenges together (CX 3459) and the high concentration in cough drops which Nielsen reports for both food and drug stores (CX 1463), it is reasonable to infer that concentration will be high in all outlets including those not sampled by Nielsen or DKK. [35]

#### Competitive Injury

72. Warner-Lambert has been a market leader in solid-form cough preparations. In addition to Smith Brothers cough drops, Warner-Lambert acquired Hall's Mentho-Lyptus cough tablets in 1964 and has steadily increased its sales from \$3.7 million in 1968 to about \$6 million in 1970 (CX 1508; CX 1481). In 1969, Warner-Lambert ranked second in cough drop sales with a market share of approximately 23 percent. In addition, with its Listerine lozenge products it had 20 percent of cough lozenge shipments in 1968 (CX 1464). Parke, Davis had 6.4 percent of cough lozenge shipments that year. In view of the fact that the merger gave Warner-Lambert and Parke, Davis a combined 29.7 percent share of cough drops and lozenges against a background of high concentration, the Commission finds that injury to competition has been demonstrated in this line of commerce. The loss of Parke, Davis' as an independent firm is particularly detrimental to competition in view of the fact that it priced its Medicated Throat Discs considerably lower than other brand name lozenge cough products sold directly in competition with it on shelves in drug stores. Medicated Throat Discs with 60 discs in a box sold at a retail price around \$.37. Merck's Sucrets is described in the record as selling at \$.98 for a box of 55 discs. Squibb's "Spec T" lozenges were packaged with 24 discs for \$1.98 and also 10 discs for \$1.00 (CX 1573). Warner-Lambert's lozenges were also priced above Parke, Davis' product.

## D. COLD REMEDIES

73. A cough, of course, can easily occur with a cold and frequently does. Yet coughs arise from many conditions not associated with colds. When they do occur with colds, they usually follow the onset of the nasal symptoms with some lapse in time. There is an industry and public recognition of a distinction between "cold preparations," and "cough preparations," *i.e.*, the latter are primarily designed to relieve against coughs in general or coughs due to colds or allergies. There is no "cure" for a cold and treatment by taking a "cold remedy" is therefore directed at relieving against the nasal symptoms of a cold, *i.e.* nasal swelling, stuffiness or excessive nasal secretions and postnasal drip. Some products are promoted as remedies for both nasal symptoms of a cold *and* coughs due to colds (referred to herein as "cough/cold preparations") and are considered as part of both the cold remedies market and the cough remedies market.

[36] 74. Warner-Lambert marketed several cold remedies in 1969 and 1970: Sinutab and Sinutab II, Super Anahist Tablets, Sinubid, Listerine Cold Tablets, and Nilcol, a cough/cold preparation introduced in September 1970. Parke, Davis marketed three cold remedies during that time: Coryza Rx A Richards CCT tablets and Rhinitis Full Strength CCT tablets, two old products with *de minimis* sales and Cosanyl-DM Cough Syrup (Improved Formula, containing nasal decongestant). In addition, complaint counsel attempt to classify Parke, Davis' prescription cough syrups, Benylin Expectorant and Ambenyl Expectorant, as cold remedies. Respondent contends that these syrups are not substantially used for treating nasal symptoms of the colds and therefore do not fall within the cold remedies market. Both Ambenyl and Benylin were included by complaint counsel in the cough remedies market, *supra*. This was clearly correct as they are promoted for the "control of cough due to cold or allergy." As indicated below, the record, however, does not support classifying them also as "cold remedies" *i.e.*, significant treatments for nasal symptoms of colds.

75. Benylin Expectorant contains the following ingredients: (a) *Benadryl*, which is an antihistamine useful in combatting an allergic component in whatever condition is being treated. Specifically, since Benylin Expectorant is indicated "as an antitussive and expectorant for control of cough due to cold or allergy," the function of the Bendryl in this particular preparation would be to deal with cough of allergic origin. In a cough due to a viral infection and resultant nasal congestion and runny nose, the Benadryl would probably not be effective, although it may have some drying action on the nasal

passageway (Tr. 3720). Benadryl also has as an approved claim an antitussive action, and this is the primary purpose for its inclusion in the product (Tr. 3616, 3618) even though some authorities question its effectiveness as an antitussive (Tr. 3720). (b) *Ammonium chloride* and *sodium citrate*, which are expectorants that stimulate bronchial and nasal secretions and act as lubricants by thinning out more viscous secretions (Tr. 3719). The amounts in Benylin Expectorant are subtherapeutic (Tr. 3618), but expectorant action was the rationale for their inclusion when the product was originally formulated (Tr. 3617). (c) *Chloroform*, which is designated as an anesthetic for the throat (Tr. 3719), but is probably just a flavoring agent in the product (Tr. 3618; Chusid 3719). (d) *Menthol*, which is for flavoring. (e) *Alcohol*, which is the vehicle that renders the other ingredients soluble (Tr. 3617; Tr. 3719).

[37] 76. Ambenyl Expectorant differs from Benylin Expectorant only in that (1) it replaces sodium citrate with the expectorant potassium guaiacolsulfonate, (2) adds Ambodryl (bromodiphen-hydra-mine hydrochloride), a derivative of Benadryl, and (3) adds codeine, a potent central nervous system antitussive (RX 2401; Tr. 3721). Ambenyl and Benylin have essentially the same action, with the exception that Ambenyl has more of an antitussive effect due to the addition of codeine.

77. It is undisputed that antihistamines alone are of no use in combatting nasal congestion resulting from a viral infection and are therefore not considered specific remedies for the common cold. Furthermore, combining an antihistamine with antitussives and expectorants does not give the antihistamine any more anti-cold effectiveness than it would have alone (Tr. 3724). For these reasons, in an ordinary viral cold situation (*i.e.*, absent any allergic element), the antihistamine components of Ambenyl Expectorant and Benylin Expectorant contribute nothing to combatting the cold's symptoms (Tr. 3725).

78. Dr. E. Leslie Chusid, an expert in pulmonary diseases who teaches, publishes, and consults extensively in the field, testified that he is aware of no physician who prescribes either Ambenyl Expectorant or Benylin Expectorant to combat congestion caused by the common cold. Dr. Mickey C. Smith, Chairman of the Department of Health Care Administration at the University of Mississippi, testified that in several years as a practicing pharmacist, during which he filled a number of prescriptions for both Ambenyl and Benylin, these products were prescribed for cough. Frequently, they would be prescribed as concomitant therapy with an antibiotic or a decongestant/antihistamine combination. Complaint counsel's expert pharma-

cologist, Dr. Standaert, testified that those who would use Ambenyl and Benylin as cold remedies would be doing so “[i]n spite of the best teaching of we pharmacologists” that antihistamines are not effective in such situations (Tr. 924).

79. Data derived from the National Disease and Therapeutic Index strongly confirm the observations of these experts. They show that from 1969 through the first half of 1973, office-based physicians prescribed Ambenyl Expectorant for cough approximately 87.9 percent of the time, and for cold only 6.6 percent of the time (RX 2229). Similarly, during the same time period, these physicians prescribed Benylin Expectorant for cough approximately 87.2 percent of the time, and for cold only 5.3 percent of the time (RX 2231). Parke, Davis’ journal advertising and detailing of Ambenyl and Benylin Expectorants reveal that they have both been promoted *solely* for cough.

[38] Industry classification treat Ambenyl and Benylin neither as a “cold preparation” or a “cough/cold preparation,” but classify them only as “cough preparations” (RX 1495; 1498) because they lack a decongestant (Tr. 3308).

#### Competitive Effect

80. Since Ambenyl and Benylin are not cold remedies, Parke, Davis’ share of the cold market is *de minimis*. Its Coryza and Rhinitis tablets had combined 1970 factory sales of \$14,000. Their sales decreased at an annual rate of 10 percent during the four previous years (CX 1652). Its Cosanyl-DM Cough Syrup (Improved Formula), containing a decongestant, was introduced on September 1, 1970 (CX 1701). Its annual factory sales appear to be approximately \$214,000 (calculated from CX 1472). DKK reports 1970 sales of Cosanyl-DM generally (presumably including the old non-decongestant formula) of \$368,000. According to DKK, Parke, Davis had 0.04 percent of the cold market in 1969 and — using the \$368,000 figure for Cosanyl-DM — 0.16 percent of that market in 1970 (RX 2046). Furthermore, the record shows that Parke, Davis has no unusual competitive potential in the cold remedies market.

Warner-Lambert’s position in the cold remedies market fell from 9th in 1969 to 10th place in 1970, although in each year it accounted for approximately 4 percent of the market. Concentration in the cold remedies market is at a moderate level. Four-firm concentration in the market declined from 46.98 percent in 1969 to 44.80 percent in 1970, while eight-firm concentration decreased from 70.09 percent to 69.03 percent (RX 2045). Market shares are well distributed. In both 1969 and 1970, seventeen firms had more than 1 percent of the market (RX 2045-46).

The Commission concludes that, based on the above facts, there has been no showing of violation of Section 7 in the cold remedies market. [39]

#### E. BRONCHIAL DILATORS

81. Bronchoconstriction or bronchospasm is a condition in which the smooth muscles of the air passages contract and make it difficult for the individual to move air in and out of the lungs. It is often associated with allergic reactions, asthma, and chronic respiratory diseases such as emphysema. At the onset of an attack the individual feels a tightening in the chest and an inability to breathe properly, accompanied by a whistling or wheezing sensation. If the attack continues, he becomes less oxygenated and this in turn is reflected in a rapid heart rate. In addition, he may experience a change in cardiac output, begin perspiring, and encounter palpitations and a constricting sensation in the throat and bronchial tubes which causes a degree of anxiety and panic.

82. The drugs employed to give symptomatic relief of bronchoconstriction and bronchospasm are generally referred to as bronchial dilators. Depending on the substance involved, bronchial dilators can be administered orally (in solid or liquid form), by aerosol inhalation, or by injection. The therapeutic use to which bronchial dilators are put depends on their dosage form. Oral preparations are used primarily in maintenance therapy and also in aborting mild, low-grade attacks. The inhalants are used to terminate acute attacks or to forestall imminent attacks. Injectable epinephrine is used as a last resort when other medication has failed or by people prone to sudden life-threatening attacks.

83. Over 99 percent of Warner-Lambert's 1970 factory sales of bronchial dilators are accounted for by *oral* preparations. These products are: (a) *Tedral*; (b) *Cholarace*; (c) *Choledyle*; and (d) *Brondecon*. In addition to these oral preparations, Warner-Lambert markets an isoproteranol inhalant, *Nebair*, which accounts for only about 0.6 percent of Warner-Lambert's bronchial dilator sales. Almost 99 percent of Parke, Davis' 1970 factory sales of bronchial dilators were accounted for by four *injectable* preparations (CX 1811, 1835-36); three containing epinephrine, one ephedrine. The remaining 1.2 percent was accounted for by an epinephrine inhalant and an oral ephedrine product.

84. Since the Warner-Lambert inhalant product and the Parke, Davis inhalant and oral products all have *de minimis* sales, the primary issue in this alleged submarket is whether oral products, like Warner-Lambert's, [40] and injectable products, like Parke, Davis', compete in



the same market. As indicated below, however, the record shows that these products are not interchangeable in medical practice and usage and, therefore, do not substantially compete.

85. The oral preparations, because they are taken through the digestive system, have a delayed onset of action and a prolonged effect. They are, therefore, useful primarily in prophylactic, or maintenance, therapy. (Tr. 785; 2026). In addition, in the event of a mild or very low-grade attack, if the patient recognizes its onset in advance, he can also take an oral preparation in an attempt to abort it. An example of such an oral preparation is Warner-Lambert's Tedral. In its various forms, it has an onset of action of 15 to 20 minutes, and, except for the sustained-release form designed to be taken twice daily, has a duration of effect of three to four hours. It is used primarily as a maintenance medication, to be taken periodically throughout the day to prevent bronchoconstriction from occurring. (Tr. 2026; 3728). As maintenance therapy, it can be prescribed either during the entire year or only during an individual patient's "asthma season." (Tr. 3728). Tedral can also be used at the onset of an attack in an attempt to ward off further symptoms. (Tr. 3728). However, if such treatment does not terminate the attack or the symptoms become more severe, some further medication would have to be employed. In this regard, the package insert for these formulations states that they "are adjuncts in the total management of the asthmatic patient. Acute or severe asthmatic attacks may necessitate supplemental therapy with other drugs by inhalation or other parenteral routes." (CX 1815, 1817-18).

86. Injectable epinephrine is not used as a maintenance therapy and would not be thought of as a maintenance-type medication. (Tr. 3729). Nor is it ever used at the onset of an attack. Because of its very significant side effects, injectable epinephrine is reserved for those situations in which the benefit to the patient outweighs the risk of these side effects. (Tr. 929). In practice, therefore, the injectable form of epinephrine is used as a last resort by a patient who has tried and failed to abort an attack with other medications. Following his failure to abort an attack on his own, the patient will go to a hospital emergency room or his physician's office for an injection of epinephrine. In addition, severe asthmatics susceptible to sudden, serious attacks are sometimes given injectable epinephrine to carry with them or to keep at home, since they may not have sufficient time to go to a physician's office or emergency room. In such cases, the injection [41] may be administered by a spouse. (Tr. 928-30; 3729-30). Even in the case of the severe asthmatic, however, such a lay-administered injection would be used only as a last resort. (Tr. 930; 3729). In addition

to its use as a bronchial dilator, epinephrine is employed in cases of acute anaphylactic shock and in some cardiovascular cases. (Tr. 927).

87. While Tedral and other oral products are carried by patients for use as maintenance therapy and in suppression of mild attacks, the Parke, Davis injectables are sold either to hospitals or to pharmacies for turnover sales to physicians, dentists and veterinarians for emergency use. In pricing Tedral, Warner-Lambert does not take into consideration the price of epinephrine. There is no evidence that the industry recognizes "bronchial dilators," including oral, inhalant and injectable preparations as a single submarket. DKK, on which complaint counsel rely as evidence of industry recognition in other submarkets, does not classify epinephrine in the same category with the other bronchial dilators.

#### Competitive Effect

##### (1) *No Elimination of Substantial Existing Competition*

88. In a bronchial dilator market excluding sales of injectable epinephrine, the sales and market share of Parke, Davis are *de minimis*. DKK ranks Warner-Lambert and Parke, Davis as follows in such a market:

	1969		1970		1971	
	\$000	%	\$000	%	\$000	%
Overall market	50,983	100.00	56,581	100.00	61,224	100.00
Warner-Lambert	9,318	18.27	10,164	17.96	10,871	17.76
Parke, Davis	18	0.03	18	0.03	24	0.04

The sales shown for Parke, Davis represents only their sales of ephedrine preparations. Including the sales of Parke, Davis' other noninjectable product, its epinephrine inhalant would not materially change this result. Even in the market as defined by complaint counsel, there is no lessening of competition, since the different therapeutic uses of the oral and injectable products mean that they are not interchangeable in use and, therefore, are unable to provide competition against one another. Because of this lack of competition between the products, the market shares as calculated by complaint counsel --- 18.1 percent for Warner-Lambert and 1.5 percent for Parke, Davis (CX 1862) --- have no competitive significance. [42]

##### (2) *Loss of Parke, Davis as a New Competitor is Not Likely to be Significant*

89. Complaint counsel rely, as evidence of Parke, Davis' potential

to expand, on various documents concerning Parke, Davis' dealings with Premo Labs (CX 3016-17) involving a possible purchase of oral bronchial dilators for resale. There is no particular reason to believe, however, the company would be successful in substantially expanding its toehold in this market. Parke, Davis' past failure to expand its toehold position in the bronchial dilator submarket is typical of the experience of many other ethical pharmaceutical companies. Sixteen firms among the top 50 ethical companies marketed bronchial dilators at some point during the period from 1958 to 1971 without ever attaining as much as 2 percent of the market during any of the six reported years. By 1971, only two of these sixteen firms had reached even the 1 percent level, even though 12 of them had marketed a bronchial dilator at least as early as 1963. There appears to be no shortage of firms in a position comparable to Parke, Davis.

#### F. IRRITANT LAXATIVES (ETHICAL)

90. Laxatives are products which stimulate or ease defecation. They are generally self-prescribed and can be purchased without a prescription. They are also prescribed by doctors for constipation, before certain X-ray procedures and certain kinds of surgery. Many authorities believe that laxatives are overused outside physician-prescribed usages. A number of laxatives are promoted directly to the public through the media, while others are ethically promoted. Regardless of the method of promotion, all laxatives are usually shelved together in retail outlets. (Tr. 3636-37).

91. Laxatives contain ingredients which are classified as irritants, salines, bulk formers, oils and emollients, and stool softeners. A number of laxatives combine ingredients from the different pharmacologic categories. Warner-Lambert and Parke, Davis both market laxatives.

[43] 92. Complaint counsel allege that irritant laxatives promoted ethically constitute a relevant product market. They further contend that within this alleged market, the merger has eliminated substantial existing competition. Respondent contends that complaint counsel's submarket definition excludes many therapeutically and economically interchangeable products; that there is no basis in the record for classifying Warner-Lambert's combination product, Agoral, as an irritant; and that even assuming complaint counsel were otherwise correct, the merger still would have no substantial anticompetitive effect.

## Lack of Public Recognition

93. The public does not recognize *irritant* laxatives as distinct from others. All of the evidence establishes that the layman is not aware of the pharmacologic distinctions among laxative ingredients and so cannot distinguish so-called irritants from others. The package inserts do not provide this information; in fact, the terms “irritant,” “irritant ingredient,” or “irritant laxative” do not appear in any of the package inserts for laxatives which contain irritant ingredients. In every case the product is described simply as a “laxative” or “cathartic.” Moreover, nowhere in Parke, Davis’ marketing documents does the term “irritant,” “irritant ingredient,” or “irritant laxative” appear. The only distinction among laxatives found in these documents is between Parke, Davis’ old-fashioned laxatives and “the ‘newer’ type laxatives with a stool softener [that] are now dominating the market.” (CX 2002, 2005). Nor do laxative advertising or retail shelving practices differentiate among irritant and other laxatives. The fact that the public does not recognize so-called irritants as distinct from other laxatives is significant because, outside of hospitals, laxatives are primarily self-prescribed. An ethical-proprietary distinction is not competitively significant for laxatives where the consumer chooses the product (and not a physician) since OTC and proprietary laxatives are featured side-by-side on the same retail shelves.

94. Although most purchases of laxatives are not by a doctor’s prescription, physician-ordered use of laxatives [44] is not *de minimis* as respondent suggests. In a one year period over 12 million physician or recommendations for laxatives were made. Recognition of an “ethical” subdivision of laxatives is therefore undoubtably justified since most physicians do not like to prescribe for patients “popular” laxatives that have been advertised on television or radio (Tr. 1939; RX 2414-16). However, among physician-directed uses of laxatives the evidence is not persuasive that *irritant* laxatives constitutes a meaningful submarket. While, as noted, there are pharmacological classifications for various laxative ingredients, many laxative products are interchangeable in actual medical usage. While one expert attributed an advantage to irritant ingredients as being “sure fire,” (Tr. 809) another testified that salines (not classified as “irritant”) are preferred for this purpose (Tr. 3363). In terms of safety and side effects, there is no substantial difference. (Tr. 3362). Also, complaint counsel’s expert witness testified that a product containing *combinations* of irritants and other ingredients, such as Warner-Lambert’s Agoral, would not be classified with “sure-fire” types. (Tr. 951-52). In fact, Agoral is not classified in DKK reports as an “irritant” laxative.

Under complaint counsel's market definition and treatment of Agoral as an irritant laxative, Warner-Lambert would be ranked eighth in 1969 with 2.8 percent of sales, and Parke, Davis seventh with 3.7 percent.

95. However, complaint counsel have not demonstrated by a preponderance of the evidence that their proposed designation of Agoral to this submarket is appropriate. Nor is there any violation in any overall laxative market. Neither party had as much as 2 percent in the overall market or ranked within the top 12 firms.

[45] It is concluded that the record will not support a finding of substantial lessening of competition in any laxative market as a result of the merger.

#### G. EMOLLIENT/PROTECTIVE PREPARATIONS PROMOTED ETHICALLY

96. Ethical emollient and protective dermatological preparations are creams, lotions, and ointments used to treat extremely dry skin conditions which require a high degree of lubrication. Such preparations tend to have a lipid fat content of 12 percent or more and thus differ from the less greasy proprietary products which have a much lower lipid content. As indicated by the name ascribed to this market, products within it must contain not only emollient ingredients but also ingredients which form a protective barrier that retains moisture and guards the skin from the elements. Products within this market are promoted to dermatologists since, for the most part, patients with dermatosis severe enough to warrant their use either seek the advice of a dermatologist or are referred to one by a general practitioner.

97. Respondent has admitted that these preparations constitute a relevant line of commerce. There is a dispute, however, as to what products are properly within it. Complaint counsel and respondent agree that the market includes the following products of Warner-Lambert's subsidiary Texas Pharmacal, having 1970 sales of \$2,072,000; Cetaphil Lotion; Lubath and Lubath ML; Lubriderm Bath Oil; Cream and Lotion; and Phorsix Cream and Lotion. The parties also agree that the market included the Parke, Davis products Dermalac, Cold Cream, and Benzoin Compound Tincture USP, with total 1970 sales of \$15,000. In addition, complaint counsel contend, and respondent denies, that the market should include the Parke, Davis product, Aeroderm, and ointment bases manufactured by both parties. Aeroderm had 1970 sales of \$104,586. If ointment bases were included in the market, Parke, Davis' sales would increase by \$127,000 to \$142,000 (not including Aeroderm), and Warner-Lambert's sales would increase by \$117,000 to \$2,189,000.

98. *Ointment bases* are vehicles in which active ingredients are

added in accordance with a doctor's particular specification. The ultimate therapeutic use of ointment bases varies, depending upon the nature of the active ingredients added to the product. They are not intended for use alone and are sold in bulk containers for use by pharmacists rather than consumers. Although DKK classifies ointment bases as ethical emollient and protectives, they should be distinguished competitively from other products within that category discussed herein.

[46] 99. Aeroderm was not classified by DKK in the Emollient and Protective subdivision of Ethical Dermatologists; instead, DKK included Aeroderm in a subdivision entitled "All Other." Neither complaint counsel nor respondent included its sales in the market share charts they introduced into evidence. Aeroderm was originally introduced as "Scrub Kreme" for use in the operating room area of hospitals by doctors and nurses who constantly scrub their hands. Aeroderm has characteristics, uses and customers distinct from the greasy, high lipid ethical emollients and protectives promoted to dermatologists for use outside of hospitals by patients with extremely dry skin conditions (Tr. 3419-20, 3486; 3136), and it is not considered competitive with such products (Tr. 3133-34).

100. It is clear that no violation has occurred in this market. Universe sales totaled \$16 to \$17 million in 1969 and 1970 with Warner-Lambert's market share between 12 and 13 percent, making it the second ranking firm. Parke, Davis' market share was unranked, with one-tenth of one percent in 1969 and .09 percent in 1970. If ointment bases are included, Parke, Davis' share would increase to .64 percent in 1969 and .76 percent in 1970 (the effect on Warner-Lambert would be equally *de minimis*). If Parke, Davis' sales of Aeroderm were included, the latter's share would increase to no more than 1.3 percent for 1970. Even this overstates the case for a horizontal violation in this market, since Aeroderm was not a successful product and was withdrawn from the market in October 1972, after nearly four years of virtually flat annual sales slightly in excess of \$100,000.

101. Nor can Parke, Davis be viewed as an important potential entrant into the market. Parke, Davis carried on no research in the dermatological area. In addition to the top eight sellers of ethical emollient and protective dermatological preparations, in 1970 DKK reported 77 other sellers, many of which appear to have the resources and capabilities at least comparable to Parke, Davis.

[47] Both in terms of promotion and product formulation, barriers to entry are low. Since ethical emollient and protective preparations are promoted solely to a small group of 3,000 dermatologists (Tr. 3417), it is undoubtedly possible to achieve effective nationwide promotion with a

small group of detail men. The lack of significant entry barriers is confirmed by the important role that small dermatological specialty companies play in this industry.

#### H. ANTI-ANGINAL DRUGS

102. Angina pectoris is a pain in the chest which is caused by a lack of adequate blood supply to the heart. In contrast to a full-fledged "heart attack," angina is a more transient affair with little or no heart damage. This cardiac malfunction, with concomitant symptomatic pain, occurs if the work demanded of the heart is greater than can be supported by the oxygen available from the blood supply. Traditionally the most common drug therapy for angina pectoris has been the administration of organic nitrates. These are combinations of nitrogen, oxygen and carbon whose basic pharmacological action, is to relax the smooth muscle of the blood vessels.

103. Since anginal attacks are usually unannounced and brief (ranging from a twinge to a pain lasting at most three to five minutes), the timing of an anti-anginal drug's action (both onset and duration) is of importance and this, in turn depends on the route by which it gets into the bloodstream. In order to understand the market definition issues raised by each party, it is necessary to set forth the ways in which different anti-anginal drugs are administered and their intended purpose.

[48] (a) *Inhalation*. The fastest method of administration is by inhalation, the breathing of a vaporized nitrate into the lungs, whence it moves into the blood stream, usually in well under a minute. The only therapeutic nitrate, adaptable to administration by inhalation is amyl nitrate, which despite its swift action, is not a preferred antianginal drug, partly because of its unpleasant, socially unacceptable smell and partly because of great difficulty in controlling the amount of the dose (which depends in part on how the patient holds it to his nose and how big a breath he takes).

(b) *Sublingual or buccal administration*. Almost as fast as inhalation is the sublingual or buccal administration of a nitrate ("sublingual" meaning "under the tongue" and "buccal" meaning "within the cheek"), in either of which cases a tablet is dissolved in the mouth and from there absorbed through the membranes of the mouth directly and immediately into the blood stream. The nitrates which can be formulated for sublingual (including buccal) administration are nitroglycerin, isosorbide dinitrate and pentrinitrol, sometimes called petrin.

(i) *Short term abortive use of sublingual nitrates*. Because of their rapid absorption into the blood stream these particular nitrates, when

administered sublingually can be used to abort an anginal attack even if it has been already started. This is probably the most common use of these antianginal drugs.

(ii) *Short term prophylactic use of sublingual nitrates.* Sublingual administration of nitrates may also be employed preventively in situations where the attack will probably follow shortly, as when the patient can reasonably anticipate a possible attack because he is about to undertake strenuous exercise or undergo emotional excitement. Another preventive use for sublingual nitrates involves those patients who get an advance (“prodromal”) warning of a coming attack and immediately take a rapid acting pill to relax the smooth muscle of their blood vessels before anginal pain begin. The number of times tablets are taken for short term preventive use may, in fact, exceed the number of situations where a patient gets a real “prodromal” warning because nervous patients sometimes misinterpret other sensations as “prodromal” warnings. (Tr. 1879). [49]

(iii) *Long term prophylactic use of sublingual nitrates.* Beyond actual or misinterpreted “prodromal” warnings, it is estimated by Warner-Lambert’s former cardiovascular research director, on the basis of daily tabulations and studies conducted regularly by Warner-Lambert, that something like 5-10 percent of all nitroglycerin users take large quantities — up to 50 or even 100 nitroglycerin pills daily — in a nervous hope of thereby avoiding the feared attacks (Tr. 1880). While taking as many as 50 to 100 sublingual nitrate pills a day is by no means an approved medical practice (Tr. 1893), the fact remains that such continuous “pill-popping” by unduly apprehensive angina patients must be recognized as a possibly misguided but real lay use of sublingual nitrates for continuous prevention of anginal attacks.

(c) *Oral administration.* A nitrate may also be administered orally, that is, by swallowing it and getting it into the blood stream through the stomach. However, it ordinarily takes from 15-20 minutes to 45 minutes or an hour for a nitrate taken orally to get into the blood stream. Consequently oral administration is not employed to relieve an anginal attack which has already begun. As a result of the same slow absorption into the blood which makes a nitrate taken orally have a slower onset of action than one taken sublingually, the nitrate administered orally yields substantially longer duration of action and thus only preventive protection against anginal attacks. There is a wide range of duration of action and protection among nitrates taken orally: from about four hours to six to eight to twelve hours per tablet. Some nitrates such as pentaerythritol tetranitrate (Warner-Lambert’s popular (“Peritrate”)) are so insoluble that they are adapted only to oral administration. Another group of anti-anginal products are “beta



blockers," which are unrelated to nitrates, but perform similarly to oral nitrate preparations.

104. Complaint counsel's anti-anginal drugs submarket purports to include both products which are designed to abort an anginal attack and oral preparations which are designed for long-term prophylaxis. The former thus include sublingual nitroglycerin, sublingual isosorbide dinitrate, and amyl nitrate. The latter consist of pentaerythritol tetranitrate (PETN) beta blockers, and oral forms of isosorbide and sustained-release nitroglycerin preparations. Parke, Davis markets only sublingual nitroglycerin; Warner-Lambert markets only PETN under [50] name Peritrate. Respondent contends that preparations used to *abort* an anginal attack, principally sublingual nitroglycerin, do not belong in the same submarket as preparations which serve only a long-term prophylactic purpose. Complaint counsel contends that competition exists, nevertheless, as the patient may either wait for an anginal attack to improve or occur, in which case he would be relegated to using a sublingual nitrate, or he or his doctor may try to reduce the number of attacks in advance by regular doses of long-acting oral nitrates or beta blockers. Considerable evidence was placed in the record and relied upon by both parties in support of their respective positions, consisting, *inter alia*, of medical practices by physicians, comparative efficacy of oral nitrate regimens (a subject of intense debate in the profession), promotional literature of oral nitrates, wide price disparity and lack of price sensitivity between the long and short-acting anti-anginal products. We find however, that is unnecessary to determine whether these two types of products constitute a single end-use product market, since even assuming they do, the record would not support a finding of violation.

#### Market Size and Structure

105. Total purchases of all anti-anginal drugs by U.S. drug stores and hospitals, which by stipulation here are to be treated as a reasonable approximation of any U.S. anti-anginal drug manufacturing market, were about \$55.1 million in 1969 and \$61.8 million in 1970. Warner-Lambert's 1969 sales of its oral nitrate, Peritrate were \$23 million, giving it a market share of 41.8 percent. Because [51] of inroads by the earlier appearance of beta blockers in the U.S. market, Warner-Lambert's share dropped to 36.5 percent in 1970 (\$22.6 million in sales). In 1971, Warner-Lambert was for the first time in many years passed in rank as the leading seller by American Home Products, the seller of Inderal, a beta blocker (RX 1766). Parke, Davis sales of sublingual nitroglycerin amounted to \$66,000 in 1969 and \$130,000 in 1970, giving it a market ranking of 0.1 percent and 0.2 respectively,

clearly too *de minimis* to constitute a basis of violation on the ground that actual competition has been eliminated.

106. Nor is there sufficient basis for predicting that Parke, Davis would substantially improve its *de minimis* market position in an anti-anginal drugs submarket. Its market share in this submarket has historically been small. This is not an atypical performance for a Parke, Davis generic product. Parke, Davis constantly evaluates its generic product line and has added products to it over the years. Among the products it considered adding to that line was PETN (Tr. 3582). Parke, Davis determined not to add PETN because it felt that there was little generic demand for this product; it is a highly controversial drug; and it has only a "possibly effective" rating by the FDA. Even if PETN had been available to Parke, Davis for generic marketing, and there is no basis for assuming that Parke, Davis would have become a significant factor in the alleged anti-anginal drugs submarket. There are many companies that are existing competitors in the anti-anginal drugs submarket. DKK reported sales by over 40 companies in 1970 and by over 50 companies in 1971. Among the sellers with small market shares were many large drug companies, all of which were at least as capable as Parke, Davis of expanding their market positions. In addition to the 12 companies in 1970 with market shares of more than 1 percent, there were 28 other companies, in addition to Parke, Davis, with sales reported by DKK in this submarket.

In conclusion, we find there is insufficient evidence to find a violation of Section 7 in an anti-anginal drugs submarket.

[52] We now turn to the submarkets in which complaint counsel do not contend there has been a lessening of substantial existing competition between Warner-Lambert and Parke, Davis, but only a lessening of toehold and/or potential competition.

#### I. ORAL DECONGESTANTS

107. Sympathomimetics, or "decongestants" as they are called, shrink the swollen lining of the nose and decrease the activity of glands in the area. The overall effect is a shrinking in nasal tissue and some drying of the lining of the nasal passages. When orally administered, decongestants enter the blood stream and, therefore, reach more vessels in the naso-pharyngeal area than when topically applied; however, because oral decongestants enter the blood stream, they can have a dangerous vasoconstrictive side effect elsewhere in the body. The dosage level of oral decongestants must, therefore, be limited. Topical decongestants have the opposite advantages and disadvantages: because they are not systemic, they do not reach as deeply as the oral preparations. On the other hand, since they are non-

systemic, there is no danger of untoward vasoconstrictive side effects. Respondent's position as to this market was stated as, "While respondent does not agree that *all* oral decongestants, ranging from proprietary self-help remedies to more sophisticated prescription medications, belong in the same submarket, it elected to dispute this submarket solely on the issue of competitive injury, accepting *arguendo* complaint counsel's all-inclusive submarket definition."

108. The hospital-drugstore market for oral decongestants comprised \$180 million in 1969 and \$200 million in 1970. The oral decongestant submarket is moderately concentrated. The record shows that four-firm concentration was 43.8 percent in 1969 and 44.4 percent in 1970, while eight-firm concentration was 70 percent in 1969 and 70.3 percent in 1970. In 1969, Warner-Lambert ranked 9th in the oral decongestant market with sales of \$9.3 million in 1969 and 189 in 1970. In 1969, Warner-Lambert ranked 9th in the oral decongestant market with sales of \$9.3 million and a 5.1 percent market share. In 1970, it ranked 8th with a volume of \$10.4 million and 5.2 percent. (RX 2060). The products accounting for Warner-Lambert's position are described in Finding 74, *supra*, dealing with cold remedies. Parke, Davis entered this submarket in 1970, with sales of Cosanyl-DM Cough Syrup of \$368,000, (Finding 80, *supra*), which represents 0.2 percent of the market.

[53] 109. We fail to find that the record supports complaint counsel's contention that Parke, Davis had "unusual potential" to expand its toehold position such that the addition of Warner-Lambert's 5.2 percent market share would threaten to lessen competition in a substantial manner in this product market. Among the vast number of oral decongestant suppliers, which are not presently among the leaders, there are a large number of major pharmaceutical companies. In 1970, in addition to Parke, Davis, twenty-three of the top 50 pharmaceutical firms, including eight of the top 20, had shares of less than 1 percent in the oral decongestant market. The number of substantial existing toehold entrants is so large that the merger cannot be found to have eliminated significant competition.

#### J. SINGLE INGREDIENT ANTIHISTAMINES

110. Antihistamines are materials which act against histamine, a compound produced in the body which is released when an individual is exposed to material to which he is allergic. The primary purpose of single-ingredient antihistamines is to allay the effects of various allergic reactions associated with histamine release, such as hay fever, food allergy, animal dander and insect stings. Single-ingredient antihistamines have a similar effect on the body, serve primarily the

same therapeutic purpose, are substantially interchangeable and have the same basic pattern of side effects. There is no dispute concerning the definition of single-ingredient antihistamines as a proper submarket.

111. Antihistamine sales were \$33.8 million in 1969 and \$36.1 million in 1970. The market is highly concentrated. In 1969, the top four firms had 74.6 percent of sales, the top eight firms 95.4 percent. In 1970, their ratios were approximately the same. Parke, Davis is the second largest seller of single-ingredient antihistamines with sales of \$8.4 million in 1970 of its antihistamines, Benadryl and Ambodryl. In the past, Warner-Lambert manufactured and sold two single ingredient antihistamines. Its products were discontinued in 1969 when its sales had fallen to \$3,000.

112. The only dispute centers around complaint counsel's contention that the acquisition has eliminated Warner-Lambert as one of the most likely potential entrants. The principal evidence relied on by complaint counsel to show that Warner-Lambert is a significant potential entrant is that it has filed Abbreviated New Drug Applications (ANDA's) with the FDA on five single-ingredient antihistamine products: [54] chlorpheniramine maleate, diphenhydramine hydrochloride (two dosage strengths), and tripeleennamine hydrochloride (two dosage strengths) — three antihistamines in all. The difficulty with this line of argument, however, is that if the filing of such ANDA's makes Warner-Lambert a potential entrant, then so are dozens of other companies which, like Warner-Lambert, have filed NDA's or ANDA's for single-ingredient antihistamines. From January 1965 through April 1970, twenty-one NDA's for antihistamines were filed by fourteen companies not among the top 8 antihistamine marketers, including Alcon, American Cyanamid, Bristol-Myers, Rexall, Rorer, Sandoz-Wander, and Carter-Wallace. (RX 2290-91). In addition, from 1970 to 1973, at least 110 ANDA's for single-ingredient antihistamines were filed by at least 52 companies (not including Warner-Lambert). Eighty-six of these ANDA's were for the products of the markets two leaders: forty for Schering's chlorpheniramine maleate and forty-six for Parke, Davis' diphenhydramine hydrochloride (Benadryl) (RX 2435-55). Moreover, antihistamine ANDA's have already been approved for a number of drug companies (RX 394-95; RX 407-08).

In addition, Warner-Lambert's filing of ANDA's was for a specialized purpose not related to full-scale entry into the single-ingredient antihistamine market. These five ANDA's were among the group of ANDA's which Warner-Lambert filed covering a number of products as part of the development of its so-called "pull-pack" system of drug dispensing. (Tr. 3408-09). Under this system, designed strictly

for hospitals and extended care facilities, each dose of medicine would be individually packaged in its own dispensing cup, which would be unsealed by pulling the two component parts apart. The "pull-pack" would provide a convenient, cost-accountable, child-proof method of delivering medication from the hospital pharmacy to the patient. (Tr. 3408-09,3472-74). Many companies already market "unit dose" systems similar to the one under development at Warner-Lambert, and most major pharmaceutical companies are considering such systems. There is no evidence that Warner-Lambert is any more likely than most other major pharmaceutical companies to establish a viable position in this segment of the market.

113. Finally, there are a large number of "toeholders" already in the single-ingredient antihistamine market, many of them among the largest ethical drug houses. In 1971, forty-three companies each had sales of single-ingredient antihistamines amounting to less than 2 percent of the market. (RX 1695-99). Of these forty-three companies, sixteen were among the top 50 [55] suppliers of ethical drugs in 1970.

The Commission concludes that the loss of Warner-Lambert as a possible entrant into the single-ingredient antihistamine market would not amount to substantial lessening of competition.

#### K. ANTACIDS

114. Antacids neutralize excess stomach acid resulting from peptic ulcers, heartburn and other causes of gastric distress. Antacids are sold in a variety of dosage forms and are promoted directly to consumers as proprietary items or to doctors and other health professionals as ethical OTC's. Ethical OTC antacids such as Gelusil, Maalox and Mylanta tend to be more efficacious formulations intended for use in treatment of gastric ulcer, gastritis, hiatal hernia and other medical conditions requiring heavy, long-term antacid use. Proprietary antacids such as Roloids, Tums, Alka-Seltzer and Bromo Seltzer tend to be mild formulations intended for short-term use in treating upset stomach and heartburn. (Di-Gel is a proprietary antacid but is equivalent to Mylanta, one of the leading ethical antacids.) A large portion of the sales of the milder and proprietary antacids are in outlets such as food stores and restaurants where they are displayed near cash registers in impulse purchase areas. Proprietary antacids account for approximately two-thirds of all antacid sales. Respondent does not dispute the existence of an all antacid market.

115. The entire antacid market had total sales of \$261 million in 1969. The ethical segment is highly concentrated. The top three sellers, Rorer's Maalox (39.3 percent), Stuart's Mylanta (21.1 percent) and Warner-Lambert's Gelusil (19.4 percent) represent 79.8 percent of all

ethical sales in 1969. In the entire antacid market, the top four companies make 59 percent of all sales, the top eight companies 75 percent. Warner-Lambert is the second largest antacid seller with 18.5 percent of the market (\$48.4 million in sales). Well-known antacids made by Warner-Lambert are Roloids, Bromo Seltzer and Gelusil. Parke, Davis was "very strong" in antacids in the 1920's but lost this position (Tr. 1394). In 1960, Parke, Davis hired a new researcher to take command of the gastrointestinal products program and was charged "to put and keep Parke, Davis in the forefront" of this market (Tr. 1394). It attempted to develop new antacid products, but never marketed any of them.

[56] 116. The Parke, Davis decision not to market antacid products was part of a systematic review undertaken under Mr. Williams' direction starting in the spring of 1969. (Williams was in charge of Parke, Davis marketing at the time.) In the course of such review, the "individual marketing plan groups reviewed all the products both in R&D and product development" for the purpose of determining where the company "had the greatest opportunity for success." (*id.*). The statement in Parke, Davis' 1970 Marketing Plan that the "entire field of antacids is being reviewed to determine one that we could use" (CX 1913) is not inconsistent with William's testimony that after full review there was no interest in marketing antacid products (Tr. 3575-76). Although designated a "1970" Marketing Plan, it was obviously prepared during 1969, probably in the spring or around mid-year, as shown by the fact that 1969 sales were "forecast" on the basis of five months sales (CX 2005-06).

117. There are approximately 109 companies, in addition to the top eight antacid suppliers, which already market an antacid product. Among these existing toehold competitors are numerous firms with a competitive potential equal to or greater than Parke, Davis'. Moreover, included among the companies with toeholds in the antacid market were firms with substantial capability in ethical marketing, as well as firms with extensive proprietary experience. Of the top 50 detailing companies, 33 were active in the antacid business in 1970. Moreover, unlike Parke, Davis, which had no proprietary distribution or consumer advertising expertise, there were 14 companies among the nation's top 100 advertisers which had substantial proprietary drug sales and already had products in the antacids market but were not among the top 8 sellers. These nine toeholders were undoubtedly more capable than Parke, Davis to become significant competitors in the proprietary segment of the antacid market, and since antacid formulation is relatively easy, the same is true of proprietary manufacturers which do not already sell antacids.

In conclusion, the Commission finds that the record fails to show that Parke, Davis was more likely than others to expand into the antacid market. No probable substantial lessening of competition has been shown. [57]

#### L. PRENATAL VITAMINS

118. Prenatal vitamins are vitamins that are formulated to meet the requirements of pregnant women. Prenatal vitamins is an ethical submarket since the products are promoted to obstetricians who, in turn, recommend them to their patients. Respondent agrees that prenatal vitamins constitute a proper line of commerce. The sole question is whether the merger has eliminated legally and economically significant potential competition.

119. In 1969, the prenatal vitamin market was 14.6 million dollars, and concentrated in structure, with the top four firms, (Parke, Davis, ranking second with 15 percent of sales) accounting for 57.4 percent of the sales. The top eight firms accounted for 81.9 percent. In 1969, Warner-Lambert's prenatal vitamin, Calcisalin, occupied a toehold position in this market with 0.3 percent and \$64,000 in sales volume. After the complaint issued, the company withdrew the product from the market, allegedly rather than reformulate it to meet new FDA requirements. Calcisalin was a market failure because the excessively large tablet had to be taken six times rather than once daily.

120. Although Warner-Lambert was capable of reformulating Calcisalin into a once-a-day preparation, it states it did not do so because it viewed the market as relatively unattractive for entry. This view is confirmed by the relative maturity of the market (CX 2276), which between 1958 and 1971 experienced only an 11.94 percent increase in total volume. In dropping from the market, Warner-Lambert reached the same decision as did nine other large ethical companies which left the market between 1958 and 1971. Warner-Lambert's lack of interest in the prenatal vitamin market is consistent with its low interest and activity in the entire vitamin field. DKK reported its total sales of all vitamins in 1970 as \$53,000, including \$46,000 in reported sales of Calcisalin.

121. As shown by the fact that since 1958 nine large drug companies in addition to Warner-Lambert have left this submarket, size alone is probably an insufficient basis for identifying likely significant new competitors. A more pertinent factor is a company's position in the overall vitamin field. Even though prenatal vitamins account for less than 10 percent of all vitamin sales (RX 1704, 1708), all types of vitamins have basically the same ingredients and it would be natural to expect substantial identity between the major vitamin

manufacturers and the leaders in the prenatal vitamin field. [58] This expectation is confirmed by the fact that the top 10 vitamin manufacturers of 1970 accounted for eight of the top 10 companies in the prenatal vitamin submarket. The 9th company was the specialty firm Nion, and the 10th was Roerig which ranked 18th in overall vitamin sales. Accordingly, if this submarket should become attractive, significant entry is most likely to come from the other major vitamin manufacturers.

Complaint counsel cite no subjective evidence of Warner-Lambert's interest in re-entering this product market and, as noted, the objective evidence clearly suggests that other companies are more likely entrants than respondent. No violation of Section 7 has been shown, therefore, with respect to this market.

#### M. ANTIBIOTICS USEFUL AGAINST GRAM-NEGATIVE BACILLI

122. Infection-causing organisms are classified as, among others, gram-positive cocci, gram-negative cocci, gram-positive bacilli, gram-negative bacilli, and fungi. Within these classes there are many different micro-organisms. Infections resulting from these organisms may be treated by antibiotics, sulfonamides, and by various other chemotherapeutic agents. Each antimicrobial agent has a spectrum of useful activity against particular micro-organisms; no one agent is useful against all disease-causing organisms.

123. Gram-negative bacilli are distinguished from other infecting organisms. Gram-negative bacilli include numerous organisms, and the infections they cause may be treated either by antibiotics or by chemotherapeutic agents, such as sulfonamides. Antibiotics and other antimicrobial agents active against gram-negative bacilli are not active against *all* gram-negative bacilli (and are not effective exclusively against such bacilli but may hit gram-negative cocci and gram-positive bacilli as well).

124. About twenty different antibiotics *and* chemotherapeutic agents are active against gram-negative bacilli. An important barrier to a complaint counsel's attempt to show the existence of an overall market of "antibiotics useful against gram-negative bacilli" is that the correct drug for a specific gram-negative infection will not be just any one of the antibiotics active against one or more of the gram-negative bacilli; rather, selection of the proper antimicrobial agent requires consideration of many factors, including the seriousness of the patient's condition, his medical history, the site of the infection, previous drug therapy, and the likely infecting agent. [59] (Gleckman 1276-78, 1337-39; Finland 2938-39; Kirby 3256-57).

125. Warner-Lambert markets one gram-negative antibiotic, Coly-



Mycin (colistin or polymyxin E). Parke, Davis markets four antibiotics having some gram-negative activity: chloramphenicol, tetracycline, ampicillin, and paromomycin. None of Parke, Davis antibiotics competes with Warner-Lambert's antibiotic as the preferred drug against any particular disease. Complaint counsel contend that all antibiotic preparations — but not chemotherapeutic agents — which include a gram-negative organism within their spectrum of activity constitute a relevant product submarket. Respondent disputes that such a product grouping qualifies as a meaningful product submarket for Section 7 purposes.

#### Lack of Medical and Industry Recognition

126. The Medical Letter, Handbook of Antimicrobial Therapy, is well-recognized as an authoritative guide for physicians treating infectious diseases. It considers together all agents used in fighting infections, including both antibiotics and chemotherapeutic agents such as sulfonamides (RX 1, pp. 3-15). In recommending the drugs to be used in treating infections caused by gram-negative bacilli it does so according to the *specific infecting organisms* rather than the gram-negative group as a whole. There is no recognized "industry" of firms manufacturing such antibiotics as distinguished from antibiotics in general, and DKK does not report on a category of drugs designated or corresponding to "antibiotics useful against gram-negative bacilli." These and other evidence clearly show that while the medical profession recognizes a group of disease-causing organisms called "gram-negative bacilli," neither the medical profession nor the pharmaceutical industry recognizes a separate economic or trade entity consisting of antibiotics effective against such organisms.

#### Lack of Substantial Therapeutic Interchangeability

127. The term "antibiotics useful against gram-negative bacilli" includes a large number of antibiotics effective against one or more of the numerous infections caused by gram-negative bacilli. While all of these antibiotics are effective against one or more gram-negative bacilli, they are not all therapeutically interchangeable in medical practice. [60] There are distinct medical preferences with regard to antibiotic usage depending upon the identity of the invading organism and other factors. Each antibiotic (and each nonantibiotic antimicrobial agent), has its own "peculiar characteristics and uses" which are well-recognized. The only situation where some of these antibiotics are readily interchangeable is to initiate immediate therapy in serious infections that are suspected to be due to gram-negative organisms

pending definite identification of the organism through analysis of cultures (Tr. 1264). Even in this limited area, the only overlap in use between Warner-Lambert's and Parke, Davis' product is more theoretical than real. Although Warner-Lambert's Coly-Mycin M. is indicated in this situation, Parke, Davis Chloromycetin would not be preferred for such use, except in limited situations, owing to possibility of serious toxic side effects.<sup>8</sup>

In addition to being so broad as to include some antibiotics that are not used interchangeably in the treatment of specific diseases, the proposed grouping excludes chemotherapeutic agents which are also used against gram-negative bacilli, such as sulfonamides.

#### Lack of Anticompetitive Effect

128. Even if "antibiotics useful against gram-negative bacilli" were a product market, this merger would have no adverse effect on competition. In 1970, Parke, Davis combined sales of its four antibiotics in this submarket amounted to \$19.6 million and accounted for a market share of 5.31 percent and seventh ranking. (By 1971, its sales had fallen by over one million dollars to \$18.4 million, its market share to 4.58 and its rank to ninth.) Warner-Lambert's sales in 1970 were \$2.4 million, a million dollars less than in the previous year, accounting for a market share of 0.66 percent. (By 1971 its sales had declined an additional half million dollars to \$1.9 million, and its market share had dropped to 0.46 percent.) This market [61] share is *de minimis* and precludes a finding that existing competition is likely to be substantially lessened by the merger in this alleged submarket, especially since concentration is decreasing and there is no evidence as to any decline in the number of suppliers. To the contrary, the evidence indicates that the number of companies marketing two important antibiotics with gram-negative activity, ampicillin and tetracycline, has been increasing.

Warner-Lambert was not one of the companies most likely to expand its position in this market. Loss of substantial potential competition is not indicated. Its Coly-Mycin sales are declining due to displacement by new and superior antibiotic products (Tr. 3423-24, 3496; RX 1687). Warner-Lambert is not regarded as a leading antibiotic developer (Gleckman 1316-17, 1321; Finland 2949-52). It did not discover Coly-Mycin, its sole antibiotic product, has no antibiotic NDA's on file, has no antibiotic manufacturing facilities, and has no research capability for elaborating new antibiotics. [62]

<sup>8</sup> Chloromycetin is a systemic broad spectrum antibiotic which can cause fatal aplastic anemia. Because of this risk of side effect, it is used only in life-threatening situations (Gleckman 1250, 1261), and the weight of authority is that it should be used then only when no other antibiotic will be effective.

## N. AMPICILLIN

129. Ampicillin is a broad spectrum, semi-synthetic penicillin. Ampicillin has been extremely well accepted by the medical profession and is one of the most frequently prescribed broad-spectrum antibiotics in the United States. The term "broad spectrum," as applied to antimicrobials, refers to the fact that such drugs have a wide range of potential uses against many different kinds of organisms. Thus, ampicillin includes both gram-positive and gram-negative organisms, including both cocci and bacilli, in its spectrum. By comparison, penicillin's effort is restricted to gram-positive organisms. Ampicillin was patented by Beecham, and is sold in the United States by Beecham and licensed by Beecham to Bristol Laboratories, Inc. and Bristol-Myers Co. Bristol has, in turn, sublicensed Squibb-Beechnut and American Home Products' Wyeth Division. In addition to Parke, Davis, which purchases ampicillin from Bristol in finished dosage form, Ayerst Laboratories Division of American Home Products and Lederle distribute ampicillin which they purchase in dosage form from Beecham. A number of other companies also sell ampicillin, apparently without license. The record reveals that the ampicillin patent has been "attacked quite successfully from the standpoint of validity \* \* \*," and other manufacturers can not "come in with impunity." (Tr. 1739). Warner-Lambert has never marketed ampicillin.

130. Parke, Davis distributes ampicillin purchased in finished dosage form from Bristol. Parke, Davis commenced marketing ampicillin in 1968 (CX 2451) and has achieved a number four ranking in the market. Its 1970 sales of \$10.4 million gave it an 11.7 percent marketing share. The top four sellers are estimated to have controlled 94.7 percent of the market in 1970.

Respondent has admitted that ampicillin is a relevant end-use product market but disputes complaint counsel's contention that Warner-Lambert was a legally or competitively significant potential entrant into the ampicillin submarket.

131. The record shows that during the period 1968 to March 1976 Warner-Lambert approached Beecham, and its licensee Bristol-Myers, about the possibility of obtaining licensing and/or marketing rights to several antibiotics including ampicillin. No agreement was reached. Although [63] complaint counsel contend that Warner-Lambert's interest was cut short only by the negotiations to acquire Parke, Davis, there is contemporaneous evidence indicating that Warner-Lambert's interest was never very strong and was waning by 1969 (RX 760, CX 2486, CX 537; see also Tr. 3430-34, 3508-09). Even if we were to view Warner-Lambert as a potential entrant there is no reason to believe its

loss as a possible entrant was significant since there are a number of other drug companies that are leading sellers of other antibiotics that were not yet selling ampicillin and with equal logic could be considered potential entrants. In contrast to these companies, Warner-Lambert had no antibiotic fermentation plant. Loss of one among many potential entrants would not substantially diminish competition.

#### O. ANTI-PSEUDOMONAS DRUGS

132. *Pseudomonas aeruginosa* is a species of bacteria, gram-negative in character, which can cause relatively minor infections, such as swimmer's ear or urinary tract infections (Kirby 3249), and also life-threatening infections in a compromised host, such as the severely burned or leukemic patient. There are presently four approved antibiotics active against *Pseudomonas*: Gentamicin, carbenicillin, colistin (Warner-Lambert's Coly-Mycin) and polymyxin B. Warner-Lambert's Coly-Mycin antibiotic products include *Pseudomonas* in their spectrum of activity. (Kirby 3249; Gleckman 1265). Its systemic preparation Coly-Mycin M is, however, principally useful only in treating urinary tract infections known or suspected to be caused by *Pseudomonas*. Warner-Lambert's largest selling Coly-Mycin product is its otic preparation used for ear infections, such as "swimmer's ear." Parke, Davis' only "anti-*Pseudomonas*" product is a Chloromycetin Ophthalmic preparation to which polymyxin B has been added in order to reach *Pseudomonas* infections of the eye.

133. Complaint counsel contend that all drugs (including biologicals) active against *Pseudomonas* constitute the relevant product market. At present such drugs are limited to antibiotics and chemotherapeutic agents. They are included within the alleged market whether formulated in injectable, oral or topical form. Complaint counsel claim the merger has eliminated potential competition in this market. Respondent disputes complaint counsel's market definition, and further contends that Parke, Davis was not a significant potential entrant, and, even if it were, the merger can have no substantial adverse effect on competition in the so-called anti-*Pseudomonas* drugs market.

[64] 134. The products manufactured by Warner-Lambert and Parke, Davis are quite obviously altogether for different therapeutic applications and there is no evidence in the record that the industry, DKK or the FDA or anyone else has ever recognized this group of drugs as a separate economic entity. Even accepting this as a proper market, Warner-Lambert's share of the anti-*Pseudomonas* market in 1970 was 9.4 percent (down from 16.9 percent in 1969) and Parke, Davis' share was 0.5 percent in 1970. (By 1971 its products now

competed against two new antibiotics active against *Pseudomonas*, including gentamicin.)

135. Counsel in support of the complaint rely on the fact that Parke, Davis had filed an application with the Division of Biologics Standards on June 29, 1970 for a new antipseudomonas drug which would be used as a *vaccine*. At the time of the hearings, this application was still on file. The original application was limited to claim usefulness of the vaccine to burn-injured patients. A new claim was planned to be made that the drug is efficacious for leukemia patients as well. The evidence presented in this record shows that the proposed Parke, Davis vaccine is intended to be used adjunctively or concurrently with conventional antibiotics regimens. Assuming the application is approved, there would be little if any effect on the use of Warner-Lambert's antibiotics since they are designed for specific purposes and are rarely used on burn or leukemic patients (Tr. 2527-31). In any event, a physician would not consider the vaccine as interchangeable with antibiotics (Tr. 1303-04).

136. The record does not support a finding of likely lessening of competition in any anti-*pseudomonas* drug market due to the merger.

#### P. URINARY ANTIBACTERIALS

137. The complaint identifies as an end-use submarket "urinary antibacterials (non-sulfa)." These are defined by complaint counsel as drugs used in the treatment of urinary tract infections *exclusive* of antibiotics, sulfonamides and urinary analgesics. Included within this asserted submarket are methenamine compounds, nitrofurantoin compounds, and nalidixic acid. These compounds are principally used for treating urinary tract infections characterized as chronic recurrent symptomatic disease. Methenamine compounds are designed for chronic suppressive use only and not for eradicating an infection. [65] The nitrofurantoin and nalidixic acid compounds may also serve that purpose but are designed primarily to eradicate infections. All of these products are useful only for infections in the urinary tract.

138. Warner-Lambert markets methenamine mandelate compounds under the trade name of Mandelamine. In 1970 it had sales of \$5.6 million. In addition, it has had an NDA pending before the FDA since 1969 on another non-sulfa urinary antibacterial, oxolinic acid. At the time of the merger, Parke, Davis marketed methenamine under the trade name Uritone. It had *de minimis* sales of about \$1,000 annually according to DKK. (CX 2620). In 1973, Parke, Davis added nitrofurantoin to its generic line.

139. While respondent admitted that "urinary antibacterials (non-sulfa)" is a proper line of commerce for Section 7 purposes (Answer ¶

6H(4)), the uncontroverted evidence, including testimony by complaint counsel's expert witness, establishes that short-acting sulfonamides are not only therapeutically interchangeable with other urinary antibacterials, but are considered the drug of choice for acute urinary tract infection. (Dr. Gleckman 1314-15; see also Tr. 3257; 851-52). This evidence indicates that "urinary antibacterials (non-sulfa)" is an "artificial" and unduly narrow classification (Gleckman 1346-47).

140. Although respondent does not formally seek a broadening of the market definition to include short-acting sulfonamides, arguing their relevance only on the question of competitive injury, analysis would best be aided by defining the market to include these sulfonamides. As so defined, the market in 1969 totalled \$60,353,000. Hoffman-La Roche and Morton Norwich companies dominated sales sharing over 70 percent of total sales nearly equally. Warner-Lambert ranked third with 9.2 percent of sales (CX 3266). Parke, Davis had only \$70,000 in sales with 0.1 percent of the market.

141. In arguing that Parke, Davis was a likely significant toehold competitor or new entrant, complaint counsel rely on a new product manager's market profile of generics written in June of 1969. The profile recommended that Parke, Davis introduce some fifteen generic products, including nitrofurantoin, "allow[ing] the complete line to be promoted \* \* \*." (CX 3690). It further recommended that "the Market Research Department institute immediately a study with physicians and pharmacists to determine acceptance and degree of success \* \* \*." for the program. (CX 3695). This plan was apparently never forwarded [66] to Mr. Williams, then Director of Marketing and now President of Parke, Davis. In any event, it failed to receive the approval of the author's superior. While this plan was not approved, Parke, Davis has continued since the merger to evaluate its generic product line and to add selected generic products as they came off patent. In 1973, pursuant to such evaluation, it added generic nitrofurantoin.

142. Parke, Davis' factory sales of nitrofurantoin were less than \$50,000 in the first year of marketing (Williams 3583). Since there is no evidence in the record as to total industry sales of urinary antibacterials for 1973, there is no way of ascertaining Parke, Davis' market share in that post-acquisition year assuming it to be relevant. But relating Parke, Davis' 1973 sales to 1970 industry sales of \$60.4 million as reported by DKK, Parke, Davis would have only a *de minimis* market share. Even if we assume that a Parke, Davis independent of Warner-Lambert would have made a better showing in 1973 or afterwards than is indicated by its 1973 sales, it is doubtful that the merger can even be characterized as combining a "leading" company in the market with a potential entrant in view of Warner-Lambert's market share being

below 10 percent. Even if we take into consideration the fact it has an NDA pending on another urinary antibacterial (oxolinic acid), we would also have to consider other post-merger developments such as new sulfonamide antibacterial compound, trimethoprim-sulfamethoxazole, which was approved for marketing in the latter part of 1973 specifically for urinary tract infections (Tr. 1317-18). Studies performed in this country showed that it was more effective than sulfonamide (Tr. 1320). It is currently marketed by Hoffman-La Roche, the market leader in this field, and by another drug company. Also the patent held by Eaton (Morton Norwich) on nitrofurantoin expired in 1969 or 1970. Approval to market it can now be secured under the ANDA procedure. Likewise, the ANDA procedure is also available and has been widely used for securing marketing approval of the short-acting sulfonamides. These recent developments affecting the availability of drugs for treating urinary tract infections make it reasonable to conclude that this submarket will be more competitive in the future than it was before the merger. These developments would seem to overshadow Parke, Davis' introduction of generic nitrofurantoin.

#### Q. MOUTHWASH

143. Mouthwashes are intended for use in cleaning the oral cavity by means of rinsing and gargling. They commonly consist of ingredients which thin salivary secretions and soften material around teeth. They also include flavoring and deodorizing agents, as well as materials with purported [67] antibacterial effect. Total sales of mouthwashes were approximately \$183 million in 1969 and \$185 million in 1970. Warner-Lambert manufactures Listerine Antiseptic Mouthwash, which in 1970 had sales of \$89 million. With about 50 percent of the market, Warner-Lambert is the undisputed leader. In contrast, Parke, Davis had four non-branded mouthwash products which in 1970 had *de minimis* total sales of \$29,000.

144. Complaint counsel do not contend that Parke, Davis was a substantial existing competitor. They claim only that the acquisition ends all likelihood that Parke, Davis would have grown to be a substantial competitive factor. Respondent agrees that mouthwash is a proper line of commerce, but denies that the merger eliminates any significant potential competition.

145. The four non-branded products of Parke, Davis are an alkaline aromatic solution introduced in 1919; alkaline aromatic tablets, both white and pink, which were introduced in 1902 and 1911, respectively, and an antiseptic solution introduced domestically in 1923. The tablet formulations are available only in gallon bottles. There are no consumer package sizes of any of these products which are marketed

only for institutional use. There is no evidence that these products would be suitable for proprietary promotion or that Parke, Davis even considered such a step. No mouthwash products were included in the roughly 100 Parke, Davis products the Ted Bates Agency reviewed to assess for possible proprietary marketing.

146. During the 1960's, Parke, Davis' Product Development Department worked on two mouthwash projects. These efforts, however, ultimately led to a decision not to market a proprietary mouthwash product. The first effort was in 1961 or 1962, when product development formulated a new mouthwash utilizing a new antibacterial agent the company had discovered. This effort was dropped because of toxicology problems. Subsequently, in 1967 or 1968, product development again worked on a new mouthwash formulation. When the development work was completed, Parke, Davis' marketing personnel were notified of product availability "for any marketing interests you may be able to elicit." After a "thorough review," Parke, Davis decided against marketing a mouthwash. A contemporaneous memorandum by Mr. Williams, then Director of United States Marketing, dated March 10, 1969, explained that the "primary reason for our decision is that it would take a considerable amount of money to effectively establish this product with the consumer. Unfortunately, within the last couple of years, the market has been literally flooded with new mouthwash preparations (*i.e.*, Micrin, Scope, [68] Colgate 100, etc.) as well as the old standbys, Lavoris and Listerine. In our opinion, we could spend our advertising and promotion dollars more effectively in other product areas." (CX 2723). Thereafter, Parke Davis engaged in no further research and development in the mouthwash area. In light of the above, it seems clear that Parke, Davis was not likely to have become a meaningful competitor in the mouthwash market in the foreseeable future. Accordingly, the Commission finds no basis for a violation of Section 7 in the mouthwash line of commerce.

R. BLOOD FRACTIONS — NORMAL SERUM ALBUMIN, IMMUNE SERUM GLOBULIN, TETANUS IMMUNE GLOBULIN

147. Normal serum albumin, immune serum globulin, and tetanus immune globulin are three therapeutic blood products that are separated out of human blood plasma by a chemical process called fractionation.

(a). *Normal serum albumin (human)*. Serum albumin is an important factor in the regulation of the volume of circulating blood. In addition to its osmotic function, albumin serves as a source of protein nutrition for the tissues. As a carrier of intermediate



metabolites, it is also important to the transport and exchange of tissue products. Normal serum albumin (human) is useful in shock due to burns, trauma, crushing injuries, abdominal emergencies and other similar conditions in which loss of red corpuscles is not severe, for the purpose of restoring blood volume rapidly. It is also useful in hypoproteinemia to increase the concentration of plasma protein and volume of circulating blood and in hyperbilirubinemia and erythroblastosis fetals as an adjunct in exchange transfusions.

(b). *Immune serum globulin (human)*. Immune serum globulin is a sterile, concentrated solution of antibodies found in normal human blood. The active component is highly refined gamma globulin. Solutions of human gamma globulin have been reported to be effective in preventing infectious (epidemic) hepatitis, preventing and modifying measles (rubeola) and poliomyelitis. In addition, it has been reported effective in various degrees against German measles (rubella), chicken pox, herpes zoster, oral herpetic lesions, and as an adjunct in the treatment of various bacterial infections which do not respond well to antibiotic therapy alone.

[69] (c). *Tetanus immune globulin (human)*. Tetanus immune globulin is a sterile, concentrated solution of tetanus antitoxin as gamma globulin prepared from the blood of adults who have been immunized with tetanus toxoid. It is used to provide immediate, passive immunity to tetanus in any person who has sustained a tetanus-prone injury and who is not known to be immune to tetanus.

148. Immune serum globulin, normal serum albumin, and tetanus immune globulin are three out of some 25 or 30 different products that can be derived from the process of human blood fractionation. Such fractionation involves a complex manufacturing process of separating out various components from human blood sources; plasma or placental serum or serum from clotted blood. There are many legal as well as technical requirements to be met in order to become a therapeutic blood fractionator. The legal requirements include a license from the Federal government's Bureau of Biologics (BOB) to be manufactured, as well as a license for the product to be sold. The manufacturing license is granted only after inspection of the facility and approval of the operating staff. The technical requirements include the facility and equipment which are estimated to cost \$2 million and must be operating at freezing or below; a qualified staff to run the operation; a research and development group; and special testing to achieve quality control.

149. Parke, Davis manufactures and markets each of these three blood fractions as well as other blood fractions. Warner-Lambert has never manufactured or marketed any therapeutic blood fractions. The

three blood fractions are each admitted to be a relevant product market for Section 7 purposes. Complaint counsel contend that the merger eliminated Warner-Lambert as a potential entrant into these markets. It is respondent's position that Warner-Lambert was not a competitively significant potential entrant into blood fractionation in general or any of the blood fraction markets here in issue.

150. The total value of purchases in 1969 of the three blood fractions involved here by U.S. hospitals and drug stores as projected by DKK were as follows:

<i>Product</i>	<i>Purchases</i>
Normal serum albumin	\$7.1 million
Immune serum globulin	\$10.7 million
Tetanus immune globulin	\$2.5 million

[70] The open market for each of the three blood fractions in question is highly concentrated. In 1969, one-, two-, four- and eight-firm sales concentration in each was as follows:

<i>Product</i>	<i>1 firm</i>	<i>2 firms</i>	<i>4 firms</i>	<i>8 firms</i>
Normal serum albumin	34%	68%	87%	92%
Immune serum globulin	64%	72%	86%	97%
Tetanus immune globulin	32%	60%	91%	—

151. The Bureau of Biologics currently licenses only 18 establishments to make one or more of the three blood fractions in question. All but one are licensed to make albumin; all but five make both of the other products, too. Many if not most of the firms in the therapeutic blood fractionation business are drug companies. Current licensees include Parke, Davis, Merck, Sharp & Dohme, American Home Products' Wyeth Division, Cutter Laboratories, American Cyanamid's Lederle Division, Abbott Laboratories, Squibb, Dow Chemical, Baxter Laboratories' Travenol Division, Armour and Johnson & Johnson's Ortho Division. (CX 3355, CX 3356, CX 3358). Certain of these such as Baxter's Hyland Labs have a strong background in diagnostic as well as therapeutic blood products. Two new licensees (North American Biologics and Metabolic Inc.) are small firms with blood banking and diagnostics backgrounds.

152. To enter the business of therapeutic blood fractionation unique facilities and a qualified staff are required, as is a Federal license, if manufacturing for interstate commerce is involved. Quality control is necessary and processing research desirable. On the marketing side, "hospital know-how" is pertinent, and established access to the customers (hospitals, drug stores, doctors) is valuable. Parke, Davis has an investment of about \$2 million in plant and

equipment for human blood fractionation, excluding warehousing, labeling, packaging, quality control and other ancillary functions.

153. Parke, Davis holds Federal licenses to manufacture more different biological products than any other establishment except American Cyanamid's Lederle Laboratories. It has an extensive facility for producing biologicals, including blood serum processing at its Parkedale, Michigan laboratories, much of which was newly built in the mid-1960's. Its biologicals line in 1969 included the three blood fraction products involved here, of which it is a leading company in two of the markets (serum albumin and [71] tetanus immune globulin):

(a). *Normal Serum Albumin*. Parke, Davis markets this under the trademark "Albuspan," in a solution for use in restoring blood volume. In 1969 Parke, Davis was the biggest supplier of the open market, with about 34 percent of total sales.

(b). *Immune Serum Globulin*. Parke, Davis markets this under the trademark "Immu-G." In 1969 it was the fifth largest supplier of the open market, with about 7 percent of the total sales.

(c). *Tetanus Immune Globulin*. Parke, Davis markets this under the trademark "ImmuTetanus." In 1969 it was the second largest supplier of the open market, with about 28 percent of total sales.

154. Most of the early entrants, including Parke, Davis, Wyeth, Merck (through its acquisition of Sharp & Dohme), Lederle and Lilly possessed biologics experience with antitoxins which are based on the immunal therapy from which human blood fractions developed. These efforts were encouraged by government contracts during World War II. Squibb also became involved at this time through a Red Cross contract for dried plasma. Another group entered human blood fractionation as an outgrowth of World War II research contracts which were an extension of their veterinary business. These were Armour and Pittman-Moore. A third group of companies, including Cutter, Baxter and Abbott, entered after the development of blood extenders and human albumin. They combined their facilities and know-how for making hospital solutions, which involve large volume, sterile production, with animal serum know-how achieved by acquiring veterinary houses. The only recent entrants have been two small nonpharmaceutical companies, North American Biologicals and Metabolic Inc., which since the merger were licensed by BOB to fractionate human blood. Prior to securing their blood fractionating licenses they were already licensed in both blood banking and diagnostic typing sera. Diagnostic products that are used in blood processing, like the typing sera made by North American and [72] Metabolic, require a BOB license and are sold primarily to blood banks. There are other diagnostic products that are used merely as controls which do not

require a license and are sold primarily to hospitals and clinical laboratories. Warner-Lambert's General Diagnostics Division produces such diagnostic controls.

155. Warner-Lambert's General Diagnostics Division, with 1969 sales over \$8 million, has led the industry in the development and marketing of quality control materials for use in monitoring the accuracy of numerous diagnostic tests. General Diagnostic's technicians could not move immediately into therapeutic blood fractionation without some re-training and guidance but, if qualified and competent, they could be so trained (Tr. 3559). The hospitals which buy Warner-Lambert's diagnostic reagents are also buyers of therapeutic blood products.

In April 1969 Warner-Lambert acquired Elizabeth Biochemical Laboratory, a bifurcated enterprise which was at once a large clinical diagnostic laboratory serving Northern New Jersey and a multi-State chain of blood donation centers for the collection of human blood, blood fractions, plasmas and serums for distribution to industrial users. Elizabeth Biochemical was the Nation's "leading supplier of industrial blood plasma" (CX 257). Of total shipments of \$1,168,000 by Elizabeth Biochemical in 1967, \$290,000 were of "normal plasmas" for fractionation into serum albumin, gamma globulin and fibrinogen; \$304,000 were of "immune plasma" for fractionation into tetanus gamma globulin; \$111,000 were of "immune plasma" for fractionation into Rh gamma globulin; \$89,000 were of so-called "salvage (outdated) plasma" for fractionation into either serum albumin and gamma globulin or diagnostic control agents; and \$335,000 were of "blood-typing plasma" for processing into various "blood-typing plasma" diagnostic reagents. (CX 2835 plus CX 2840). Most of Elizabeth's plasma was thus raw material for therapeutic blood fractionation.

[73] 156. By the end of March 1969 (the same month the Elizabeth Biochemical acquisition was consummated) Warner-Lambert planners were working on a "merger approach" to Cutter Laboratories of Berkeley, California, one of the 18 Federal blood fractionation licensees. A comprehensive Warner-Lambert memorandum a little later described Cutter as a pioneer in the vaccine field which had been working with Parke, Davis in the field of "human blood fractions." (CX 2878). Cutter was said to have continued to do a lot of work over the years with specific gamma globulin and antitoxins developed from hyperimmunized human donors, which work was "quite closely related to the efforts of Elizabeth Biochemical." (CX 2878). The same memorandum pointed out that "[b]ecause of Cutter Laboratories' long time emphasis on I.V. solutions, vaccines, antitoxins and *plasma fractions*," Warner-Lambert "would expect strong representation in

this segment of the hospital market, etc.” (CX 2880; emphasis added). By the latter part of April a meeting with Cutter had been arranged. Warner-Lambert’s President (Giblin) and Executive Vice President (Bright) met with Cutter’s President (David Cutter) on April 23 “to see whether they would have any interest in joining with Warner-Lambert.” (CX 2868). Giblin and Bright talked about a “total health company” and pointed out how Cutter’s operations would tie in with Warner-Lambert’s, enabling both to grow more rapidly than either alone. (id.) Warner-Lambert later reported that its “offer” had been “turned down” by Cutter shortly after it was made. (CX 2106).

157. Having failed in its effort to acquire Cutter, Warner-Lambert next turned to Squibb, another of the 18 Federal blood fractionation licensees. This time it proposed not a merger but a processing agreement. On October 3, 1969 Warner-Lambert’s Hastings, with Executive Vice President Bright, visited Squibb “to discuss possible future relationships regarding biological products.” (CX 2886). Specifically, they were investigating the feasibility of having Squibb manufacture a line of generic blood products for Warner-Lambert (CX 2105). Warner-Lambert determined that Squibb could accept orders for the manufacture of globulins, albumin and “AHF” (anti-hemophilic fractions) early in 1970, when Squibb’s current expansion would be complete (CX 2886). However, some time in December 1969 negotiations were terminated because Squibb did not have the manufacturing time available (CX 2105). The documentary evidence does not support the testimony offered by respondent that the negotiations were primarily aimed at and conditioned upon a joint R&D program with Squibb for new blood fractions.

[74] 158. The Commission finds that immediately prior to the acquisition, Warner-Lambert had the interest and capacity to enter the normal serum albumin and tetanus immune globulin markets, that these markets were highly concentrated and characterized by substantial technological and marketing entry barriers, that Parke, Davis was a leading firm in each of these two markets, that procompetitive means of entry by internal expansion, acquisition of a toehold company or companies, or supply arrangements with an existing firm, was a feasible means of alternative entry, that the number of other likely entrants was not so numerous as to make the loss of future entry by Warner-Lambert’s insubstantial, and that entry by Warner-Lambert would have had a procompetitive effect on these markets.

159. In view of the fact that Parke, Davis, with only 7 percent of the immune serum globulin sales, was not a leading company in that market, no substantial lessening of competition in immune serum globulin is found to have resulted from the acquisition.

## CONCLUSIONS OF LAW

1. The Commission has jurisdiction of and over the subject matter of this proceeding and of respondent Warner-Lambert Company.

2. The effect of the acquisition of Parke, Davis stock by Warner-Lambert Company has been, or may be, substantially to lessen competition in violation of Section 7 of the Clayton Act, as amended, in the following lines of commerce:

- (a) Thyroid preparations
- (b) Cough remedies
- (c) Cough drops and lozenges
- (d) Normal serum albumin
- (e) Tetanus immune globulin.

3. No violation of Section 7 has been demonstrated in the other lines of commerce asserted in this proceeding.

## ORDER

This matter having been heard by the Commission upon the appeal of complaint counsel from the initial decision and upon briefs and oral argument in support thereof and opposition thereto, and the Commission having determined that an appropriate order should be issued to conform with its decision as set forth in the accompanying opinion:

*It is ordered,* That the initial decision of the administrative law judge be vacated, and that the findings of fact and conclusions of law contained in the "Opinion of the Commission" and in the document styled "Findings of Facts and Conclusions of Law" shall be adopted as the findings of the Commission in this matter.

*It is further ordered,* That within 30 days from the date of service of this order, each party shall file with the Commission a proposed form of order appropriate to the Commission's decision, together with a supporting memorandum. Thereafter each party, within ten days after receipt of the proposal of the other may file with the Commission a reply thereto.

Chairman Collier, not having participated in the oral argument in this matter, did not participate in the foregoing resolution of it.