

FEDERAL TRADE COMMISSION DECISIONS

Complaint

95 F.T.C.

IN THE MATTER OF

AHC PHARMACAL, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3017. Complaint, April 28, 1980 — Decision, April 28, 1980*

This consent order requires, among other things, a Miami, Fla. firm and its corporate president, engaged in the marketing and advertising of health related products, to cease disseminating advertisements which represent that the use of AHC Gel or any similar preparation, alone or as part of an acne control regimen, cures acne and results in a blemish-free skin; or that any such preparation is superior to other over-the-counter acne products. Respondents are required to have a reasonable basis for advertising representations relating to product performance, efficacy and results and prohibited from misrepresenting the extent or results of product testing. Respondents are further prohibited from disseminating advertisements for acne products without first disseminating prescribed corrective advertising as specified in the order. Additionally, ad substantiation must be maintained for a period of three years.

*Appearances*For the Commission: *Steven Newborn.*For the respondents: *Pro se.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission having reason to believe that AHC Pharmacal, Inc. (hereinafter "AHC Pharmacal"), a corporation, and James E. Fulton, M.D. (hereinafter "Fulton"), as an individual and corporate officer, hereinafter at times referred to as respondents, having violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. "AHC Pharmacal" is a corporation organized, existing and doing business under and by virtue of the laws of the State of Florida with its office and principal place of business located at 1609 N.W. 14th St., Miami, Florida.

PAR. 2. "Fulton" is an individual and corporate president of "AHC Pharmacal." He formulates, directs and controls the acts and practices "AHC Pharmacal," including the acts and practices described

herein, and he is the principal beneficiary of the corporation's business. "Fulton's" business address is 1609 N.W. 14th St., Miami, Florida.

PAR. 3. Respondent "AHC Pharmacal" is a privately held corporation which was organized and is maintained for the purpose of promoting and conducting the business interests of "Fulton." "AHC Pharmacal" and "Fulton" have been and now are marketing and advertising health related products, including but not limited to a product variously known as AHC Gel, AHC Pharmacal's benzoyl peroxide gel medication and b.p. gel medication (hereinafter "AHC Gel"), a product advertised for the treatment of acne. The respondents, in connection with the manufacture and marketing of said product, have disseminated, published and distributed, and now disseminate, publish and distribute advertisements and promotional material for the purpose of promoting the sale of "AHC Gel" for human use. "AHC Gel" is marketed by the respondents, both separately and as part of a program for the treatment of acne known as "Dr. Fulton's Acne Control Regimen" (hereinafter "the Acne Control Regimen"). This product, as advertised, is a "drug" within the meaning of Section 12 of the Federal Trade Commission Act.

PAR. 4. In the course and conduct of their said businesses, the respondents have disseminated and caused the dissemination of certain advertisements concerning "AHC Gel" and "the Acne Control Regimen" through the United States mail and by various means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, the insertion of advertisements in magazines with national circulations, and advertisements in the form of a booklet, entitled "Acne: A Treatable Disease" which was, and is, sent through the United States mail, for the purpose of inducing and which was likely to induce, directly or indirectly, the purchase of the product "AHC Gel," and have disseminated and caused the dissemination of advertisements concerning said product by various means, including but not limited to the aforesaid media, for the purpose of inducing and which are likely to induce, directly or indirectly, the purchase of said products in commerce.

PAR. 5. Typical of the statements and representations in said advertisements disseminated as previously described, but not necessarily inclusive thereof, are the following:

Is the ACNE Problem Finally OVER?



Acne sufferer, now specialist, has developed a new treatment* for acne control that offers young adults their first real hope for clear complexions.

"My acne started at sixteen. I tried everything from oral antibiotics to x-ray treatment, even ultraviolet light. Nothing worked. I became a Dermatologist and Ph.D. in Biochemistry in an attempt to find a cure for acne."
"After seven years of research, I discovered benzoyl peroxide (bp) gel*, a topical medication that has revolutionized the treatment and control of acne."
"Since 1973, my Acne Health Care Centers throughout the United States have treated tens of thousands of acne sufferers using my benzoyl peroxide medications. The results: over 85% of our patients (even the cystic variety) are dramatically improved within eight weeks."
"Unfortunately, our clinics can only treat a very small percentage of those that really need help."
"In an effort to reach the many acne sufferers that are often given false hope about their problem and are continually disillusioned by over-the-counter acne remedies, we have developed a very exciting **ACNE CONTROL REGIMEN**."

"If we give you the opportunity to locate your acne sufferer early, we can bring the condition under control and eliminate the possibility of facial scarring that may result from continued acne breakouts."
"I consider this acne control program to be the finest available today for the control of acne — next to being treated at one of my Acne Health Care Centers."

James E. Fulton, Jr.
James E. Fulton, Jr., M.D., Ph.D.
Founder of Acne Health Care Centers
Founder of Acne Research Institute
Diplomat, American Board of Dermatology
Fellow, American Academy of Dermatology

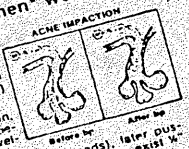


"People don't realize how emotionally painful and frustrating acne can be. For seven years my days started and ended with depression. Dr. Fulton's Acne Control Regimen has given me new hope."

Before Treatment

How Dr. Fulton's regimen* works

Acne is genetic.
Acne is clogged pores.
Normally, dead skin cells are flushed up the pores of oil glands by sebum (surface oil) and washed away.
In genetically defective skin, these cells stick — the pores become impacted — acne develops.
These impactions (whiteheads, blackheads), later pustules, which could result in permanent scarring, exist beneath the surface of the skin.
Special soaps and most over-the-counter preparations attempt to dry up oil only at the surface level. This will never help the acne problem.
Dr. Fulton's "Acne Control Regimen" actually penetrates into the pores and treats the genetic problem in two ways:
1. Kills the C-acnes bacteria which produce irritating acids in the pores and accelerates the shedding of dead skin cells, thus reducing the cohesiveness of dead skin cells.
2. Reduces the cohesiveness of dead skin cells, thus loosening and clearing up acne impactions.
THE RESULT: An opportunity now exists for the acne sufferer to find dramatic improvement.



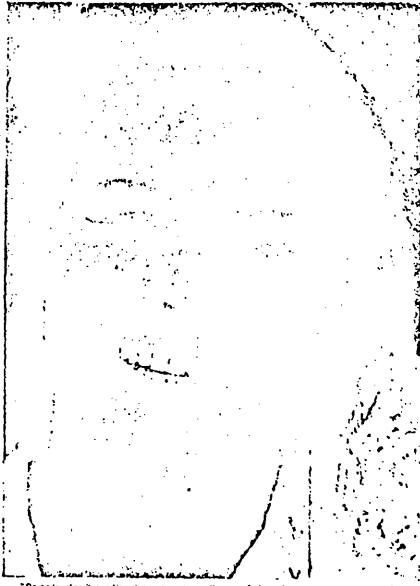
AHC PHARMACAL, INC. 1351 N.W. 16th St.
Miami, Florida 33125
complete programs of Dr. Fulton's ACNE CONTROL REGIMEN

Please rush —
which includes: (1) A 3 oz. bottle of P.P. Gel Medication
(2) Dr. Fulton's Maroon
— ACNE, A Treatable Disease!
Enclosed is \$12.95 (which includes postage & handling for each Program)

Order form with fields for Name, Address, City, State, Zip, and payment options: Cash, VISA, Money Order, or Money Order.

*Dr. Fulton's unique gel of ultra-stabilized benzoyl peroxide — P.P. applied topically. Pat. Fulton, Jr., 3,342,000, at section of benzoyl peroxide. Just. Commissioner. Pat. No. 3,191, 1974.

The ACNE Problem is Finally OVER



Acne sufferer, now specialist, has developed a new treatment* for acne control that offers young adults their first real hope for clear complexions.

"My acne started at sixteen. I tried everything from oral antibiotics to x-ray treatment, even ultraviolet light. Nothing worked."

"I became a Dermatologist and Ph.D. in Biochemistry in an attempt to find a cure for acne."

"After seven years of research, I discovered benzoyl peroxide (bn) gel*, a topical medication that has revolutionized the treatment and control of acne."

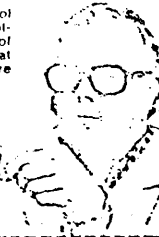
"Since 1973, my Acne Health Care Centers throughout the United States have treated tens of thousands of acne sufferers using my benzoyl peroxide medications. The results: over 85% of our patients (even the cystic variety) showed dramatic improvement within eight weeks."

"Unfortunately, our clinics can only treat a very small percentage of those that really need help."

"In an effort to reach the many acne sufferers that are often given false hope about their problem and are continually disillusioned by over-the-counter acne remedies, we have developed a very exacting 'ACNE CONTROL REGIMEN.'"

"If we are given the opportunity to reach you, the acne sufferer early, we can, in most cases, bring the condition under control and eliminate the possibility of facial scarring that may result from continued acne breakouts."

"I consider this acne control program to be the finest available today for the control of acne — next to being treated at one of my Acne Health Care Centers."



James E. Fulton, Jr. M.D.

James E. Fulton, Jr., M.D., Ph.D.
 Founder of Acne Health Care Centers
 Founder of Acne Research Institute
 Diplomate, American Board of Dermatology
 Fellow, American Academy of Dermatology

"People don't realize how emotionally painful and frustrating acne can be. For seven years my days started and ended with depression. Dr. Fulton's Acne Control Regimen has given me new hope."

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How Dr. Fulton's regimen* works

Acne is genetic.

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Normally, dead skin cells are flushed up the pores of oil glands by sebum (surface oil) and washed away.

In genetically defective skin, these cells stick — the pores become impacted — acne develops.

These impactions (whiteheads, blackheads), later pustules, which could result in permanent scarring, exist beneath the surface of the skin.

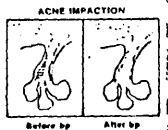
Special soaps and most over-the-counter preparations attempt to dry up oil only at the surface level. This will never help the acne problem.

Dr. Fulton's "Acne Control Regimen" actually penetrates into the pores and treats the genetic problem in two ways:

1. Kills the *C. acnes* bacteria which produce irritating acids in the pores and accelerate the clogging process.

2. Reduces the cohesiveness of dead skin cells, thus loosening and clearing up acne impactions.

THE RESULT: An opportunity now exists for the acne sufferer to find dramatic improvement.



*Dr. Fulton's unique gel of glycerin stabilized benzoyl peroxide — not applied for. Ref. Fulton, J. E., Studies on mechanism of action of benzoyl peroxide. *J. Cutaneous Med. Biol.* 9:191, 1975

AHC PHARMACAL, INC. 1351 N.W. 16th St.
 Miami, Florida 33125

Please rush — complete program(s) of Dr. Fulton's ACNE CONTROL REGIMEN

Which includes: (1) A 3 oz. bottle of b-o Medicated Soap
 (2) A 1 oz. bottle of b-o Gel Medication
 (3) Dr. Fulton's Manual
 "ACNE: A Treatable Disease"

Enclosed is \$12.95 (which includes postage & handling for each program).

VISA Check or Money Order Master Charge Bank No. _____

Credit Card # _____ Exp. Date _____

Name _____

Address _____ Apt. # _____

City _____ State _____ Zip _____

Signature _____ (M-478)

MONEY BACK GUARANTEE: If your improvement does not satisfy you, just return the empty containers for a full refund.

PAR. 6. Through the use of said advertisements and others referred to in Paragraphs Four and Five, respondents represented, and now represent, directly or by implication that use of "AHC Gel," either alone or as part of "the Acne Control Regimen," will cure acne regardless of the severity of the condition.

PAR. 7. In truth and in fact, use of "AHC Gel," either alone or as part of "the Acne Control Regimen," will not cure acne. Therefore, the advertisements referred to in Paragraphs Four and Five were and are misleading in material respects and constituted, and now constitute, false advertisements, and the statement and representation set forth in Paragraph Five was, and is false, misleading and deceptive.

PAR. 8. Furthermore, through the use of the advertisements referred to in Paragraphs Four and Five, respondents represented, and now represent that:

a. Use of "AHC Gel," either alone or as part of "the Acne Control Regimen," by persons with acne will result in skin free of pimples, blackheads, whiteheads, other acne blemishes, and scarring.

b. Use of "AHC Gel," either alone or as part of "the Acne Control Regimen," by persons with acne will help control pimples, blackheads, whiteheads, other acne blemishes, and scarring, regardless of the severity of the disease.

c. "AHC Gel," either alone or as part of "the Acne Control Regimen," is superior to all other over-the-counter acne preparations for the treatment of acne, including but not limited to other benzoyl peroxide products.

PAR. 9. In truth and in fact there existed at the time of the first dissemination of the representations referred to in Paragraph Eight no reasonable basis for the making of these representations, in that respondents lacked competent and reliable scientific evidence to support said representations. Therefore, the making and dissemination of said representations as alleged constituted, and now constitute, unfair or deceptive acts or practices in or affecting commerce.

PAR. 10. In the course and conduct its aforesaid business, and at all times mentioned herein, the respondents have been, and now are, in substantial competition in or affecting commerce with corporations, firms and individuals representing or engaged in the over-the-counter and prescription drug industries.

PAR. 11. The use by respondents of the aforesaid unfair or deceptive representations and the dissemination of the aforesaid false advertisements has had, and now has, the capacity and tendency to mislead members of the consuming public into the erroneous and mistaken belief that said representations were and are true.

PAR. 12. The aforesaid acts and practices of respondents, as herein alleged, including the dissemination of the aforesaid false advertisements, were and are all to the prejudice and injury of the public and of respondents' competitors, and constituted, and now constitute, unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the bureau proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violations of the Federal Trade Commission Act; and

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of such agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent AHC Pharmacal, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Florida with its office and principal place of business located at 1609 N.W. 14th St., Miami, Florida.
2. Respondent James E. Fulton, M.D. is an individual and corporate officer of AHC Pharmacal, Inc. and maintains an office at 1609 N.W. 14th St., Miami, Florida.
3. The Federal Trade Commission has jurisdiction of the subject

matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

I

It is ordered, That respondents AHC Pharmacal, Inc., a corporation, and James E. Fulton, individually and as a corporate officer, their successors and assigns, either jointly or individually, and the corporate respondent's officers, agents, representatives, and employees, directly or through any corporation, division or other device, in connection with the advertising, offering for sale, sale or distribution of all products do forthwith cease and desist from:

A. Disseminating or causing the dissemination of any advertisements by means of the United States mail or by any means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, which directly or indirectly:

1. Represents that use of a product variously known as AHC Gel, AHC Pharmacal's benzoyl peroxide gel medication and b.p. gel medication (hereinafter "AHC Gel") either alone or as part of "Dr. Fulton's Acne Control Regimen" (hereinafter "the Acne Control Regimen") or any other acne product or regimen will cure acne or any skin condition associated with acne.

2. Misrepresents the extent to which any product has been tested or the results of any such test(s).

B. Disseminating or causing the dissemination of any advertisement by means of the United States mail or by any means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, which directly or indirectly:

1. Represents that use of "AHC Gel", either alone or as part of "the Acne Control Regimen", or use of any other acne product or regimen by persons with acne, will result in skin free of pimples, blackheads, whiteheads, other acne blemishes, or scarring;

2. Represents that "AHC Gel", either alone or as part of "the Acne Control Regimen", or any other acne product or regimen, is superior to other over-the-counter acne preparations for the treatment of acne, including but not limited to other benzoyl peroxide products,

unless, at the time of each dissemination of such representation(s) respondents possess and rely upon competent and reliable scientific or medical evidence as a reasonable basis for such representation(s). "Competent and reliable scientific or medical evidence" shall be

defined as evidence in the form of at least two well-controlled double-blind clinical studies which are conducted by different persons, independently of each other. Such persons shall be dermatologists who are qualified by scientific training and experience to treat acne and conduct the aforementioned studies.

C. Disseminating or causing the dissemination of any advertisement by means of the United States mail or by any means in or affecting commerce, "commerce" is defined in the Federal Trade Commission Act, which directly or indirectly makes representations referring or relating to the performance or efficacy of any product or refers or relates to any characteristic, property or result of the use of any product, unless, at the time of each dissemination of such representation(s) respondents possess and rely upon a reasonable basis for such representation(s).

II

It is further ordered, That within sixty (60) days of the acceptance of this order, respondents shall cease and desist from disseminating or causing the dissemination of advertisements for "AHC Gel", "the Acne Control Regimen", and/or any other acne product or regimen, unless respondents first disseminate corrective advertisements for the Acne Control Regimen (including AHC Gel) in Sunday newspaper supplements and on radio.

A. All such Sunday newspaper supplement corrective advertisements shall clearly and conspicuously disclose, in the headline with boldface type no smaller than 48 points (one-half inch) in height, that "no product can cure acne." Nothing in the headline, or any part of the advertisement, shall in any way obscure or contradict the clear meaning of the disclosure. Furthermore, no language in said advertisement shall appear in a type size equal to or larger than the headline type size.

Said Sunday newspaper supplement corrective advertisements shall be disseminated in the following cities: Boston, MA; Atlanta, GA; Cleveland, OH; Philadelphia, PA; Pittsburgh, PA; and San Francisco, CA. Respondents may substitute cities of reasonable demographic and geographic similarity, provided that said cities are substituted on a one-for-one basis. Said corrective advertisements shall be run at least one full-page advertisement per month for a time period of three consecutive months, provided that said advertisements shall not be disseminated during the months of June, July, or August.

Respondents may elect to run two half-page corrective advertisements in the place of each and every full-page corrective advertise-

ment to satisfy their corrective advertising obligations under this part of the order. *Provided, however*, that all such corrective advertisements must be run in different weekly issues of the aforementioned newspaper supplements for any given locale, and other requirements of this order (*e.g.*, headline type size, dissemination schedule, etc.) are fully complied with.

B. All corrective advertisements which are required for dissemination by radio shall be at least thirty seconds in duration and shall begin with the unobscured announcement that "no product can cure acne." Nothing else in the advertisement shall in any way obscure or contradict the clear meaning of this statement. Said radio corrective advertisements shall be disseminated as non-consecutive spots over major radio stations (as defined below) in the following urban areas: Chicago, IL; Los Angeles, CA; Miami, FL. Said radio corrective advertisements shall be disseminated at least twice each month during the same three months as the Sunday newspaper supplement corrective advertisements, referred to in IIA, are disseminated.

For purposes of this order a "major radio station" shall be defined as a radio station which (a) has a broadcast power of at least 6,000 watts horizontal and 6,000 watts vertical, and (b) is described in its own promotional materials as being targeted at teenagers or young adult audiences and/or primarily playing rock, disco or contemporary hit music.

C. The obligation to run corrective advertisements shall not in any way alleviate other order obligations. Furthermore, such advertisements shall not represent, directly or indirectly, that the Federal Trade Commission approves, recommends or in any manner endorses the advertised product or product's advertising.

III

It is further ordered, That respondents shall forthwith distribute a copy of this order to each of their operating divisions.

It is further ordered, That each respondent notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of this order.

It is further ordered, That such respondent shall, within sixty (60) days after this order becomes final, and annually thereafter for three (3) years, file with the Commission a report, in writing, signed by

respondent, setting forth in detail the manner and form of its compliance with this order.

It is further ordered, That each respondent shall maintain files and records of all substantiation related to the requirements of Parts IB and IC of this order for a period of three (3) years after the dissemination of any advertisement which relates to that portion of the order. Additionally, such materials shall be made available to the Federal Trade Commission or its staff within fifteen (15) days of a written request for such materials.

Complaint

95 F.T.C.

IN THE MATTER OF
ELI LILLY AND COMPANY

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT AND SEC. 7 OF
THE CLAYTON ACT

Docket C-3021. Complaint, April 29, 1980 — Decision, April 29, 1980

This consent order requires, among other things, an Indianapolis, Indiana manufacturer and seller of pharmaceuticals and other chemical substances, to cease engaging in several anticompetitive practices involving the United States finished insulin industry. Additionally the order requires Eli Lilly and Co. to grant certain licenses covering its existing and future insulin-related technology to existing and prospective competitors.

Appearances

For the Commission: *William C. Holmes.*

For the respondent: *Charles E. Buffon, Covington & Burling,*
Washington, D.C.

COMPLAINT

The Federal Trade Commission, having reason to believe that Eli Lilly and Company, hereinafter referred to as "Lilly" or "respondent", has violated Section 5 of the Federal Trade Commission Act, as amended, (15 U.S.C. 45), and Section 7 of the Clayton Act, as amended, (15 U.S.C. 18), and that a proceeding in respect thereof would be in the public interest, hereby issues this complaint, stating its charges as follows:

I. RESPONDENT

PARAGRAPH 1. Lilly is a corporation organized and existing under and by virtue of the laws of the State of Indiana, with its principal executive offices located at 307 East McCarty St., Indianapolis, Indiana.

PAR. 2. Lilly's principal business is the manufacture and sale of chemical compounds and substances for use by or on living organisms — human, plant and animal. This business accounted for approximately 89% of the consolidated net sales of Lilly and its subsidiaries during the years 1972 through 1976.

PAR. 3. In 1976, Lilly's consolidated net sales were approximately \$1.34 billion, consolidated net income after taxes was approximately

\$200 million, and consolidated total assets were approximately \$1.58 billion. Sales of pharmaceuticals accounted for approximately \$761 million of Lilly's consolidated net sales in 1976.

II. NATURE OF TRADE AND COMMERCE

A. Relevant Market

PAR. 4. The relevant geographic market involved in this complaint is the United States as a whole.

PAR. 5. The relevant product market involved in this complaint is finished insulin.

PAR. 6. Finished insulin is a drug used by approximately 1,600,000 diabetics within the United States in the treatment of diabetes mellitus, commonly known as diabetes. For those diabetics who are insulin-dependent, finished insulin is the only method of treatment.

PAR. 7. The market for finished insulin has been and is expanding rapidly. In 1970, total industry sales of finished insulin within the United States were approximately \$26 million. By 1976, industry sales had expanded to approximately \$57 million, representing an increase of more than 119% between 1970 and 1976.

PAR. 8. The market for finished insulin within the United States is dominated by Lilly. Only two firms, including Lilly, account for 100% of total industry sales. Lilly alone accounted for more than 85% of total industry sales during the period from 1970 through 1976.

B. Industry Information

PAR. 9. A vital raw material in the production of finished insulin is animal pancreas glands, derived as by-products from meat slaughterhouses. Unrefined insulin and other materials are extracted from these glands in a form called "insulin salt cake." Insulin salt cake is then purified into a precipitate referred to as "insulin crystals." Insulin crystals are combined with other substances to produce finished insulin.

PAR. 10. Lilly is the only firm in the United States finished insulin industry that is fully integrated. Lilly purchases animal pancreas glands, extracts raw insulin from the glands in the form of insulin salt cake, refines the salt cake into insulin crystals, produces finished insulin from the crystals, and markets the finished insulin to hospitals and pharmacies throughout the United States for use by diabetics.

PAR. 11. Lilly purchases its requirements of animal pancreas glands from United States meat slaughterhouses either directly or through "collectors" or "brokers." "Collectors" are firms that purchase glands

from the slaughterhouses for their own accounts, trim and freeze the glands, and then sell them to manufacturers, either directly or through brokers. "Brokers," in contrast, are firms that simply arrange for the purchase and/or sale of the glands at a commission.

III. JURISDICTION

PAR. 12. At all times relevant to this complaint, Lilly has purchased and offered to purchase animal pancreas glands from meat slaughterhouses, collectors and brokers located throughout the United States, and has sold, shipped and promoted its finished insulin products to customers located throughout the United States. Lilly has thereby engaged in or affected commerce as "commerce" is defined in the Federal Trade Commission Act, as amended, 15 U.S.C. 44. Except to the extent that competition has been hindered, restrained or frustrated by the acts and practices alleged below in this complaint, Lilly has been and is in competition with other firms in the purchase of pancreas glands within the United States and in the sale and distribution of finished insulin within the United States.

A. Count I

PAR. 13. Lilly has monopoly power within the relevant market.

PAR. 14. Lilly has since at least 1952 directly and indirectly engaged in acts, practices and methods of competition that, individually or collectively, have willfully maintained its monopoly power within the relevant market and that have given it the power to inhibit, frustrate and restrain actual and potential competition within the relevant market.

Examples of such acts, practices and methods of competition include, but are not limited to, the following:

(a) Lilly has conspired with other domestic and foreign companies, including certain collectors, brokers, and other manufacturers of insulin, to:

- (1) Allocate and control the meat slaughterhouses at which pancreas glands are collected within the United States;
- (2) Allocate and control the distribution of pancreas glands collected within the United States;
- (3) Suppress potential competition in the collection of pancreas glands within the United States through such acts, practices and methods of competition as:

(i) A concerted refusal to deal with collectors and brokers not privy to the conspiracy (hereinafter "disfavored collectors and brokers");

(ii) The inducement of refusals to deal with disfavored collectors and brokers by their customers and suppliers;

(b) Lilly has acquired exclusive licenses within the United States to certain key patents in the production of insulin products, including in particular a 1952 exclusive patent license from Novo Industri A/S, a Danish insulin producer ("Novo"), that expressly precluded other insulin manufacturers from entering the United States finished-insulin market with certain key insulin products.

PAR. 15. The aforesaid acts, practices and methods of competition by Lilly have had, among others, the following effects:

(a) The discouragement of potential entry into the United States finished insulin market, including, in particular, potential entry by:

(1) The insulin manufacturers privy to the aforementioned conspiracy affecting the collection and distribution of pancreas glands within the United States;

(2) The insulin manufacturers affected by the aforementioned exclusive patent licenses;

(3) Novo Industri A/S;

(b) The creation and maintenance of barriers to competition in the United States finished insulin market through:

(1) Control of the pancreas glands needed to produce finished insulin within the United States;

(2) Control of key patents significant to effective competition within the United States finished insulin market.

PAR. 16. The aforesaid acts, practices and methods of competition constituted and still constitute unfair methods of competition and unfair acts or practices in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45.

B. Count II

PAR. 17. Lilly has since at least 1952 acquired patent rights under exclusive patent licenses where the effect has been to tend to substantially lessen competition, or to tend to create a monopoly, within the relevant market.

An example of such acquisitions includes, but is not limited to, the 1952

exclusive patent license from Novo Industri A/S referred to in Paragraph Fourteen (b), above.

PAR. 18. The aforesaid acquisitions by Lilly have had, among others, the following effects:

(a) The discouragement of potential entry into the United States finished insulin market, including, in particular, entry by:

(1) The insulin manufacturers affected by the aforementioned exclusive patent licenses;

(2) Novo Industri A/S;

(b) The creation and maintenance of barriers to competition in the United States finished insulin market through control of key patents.

PAR. 19. The aforesaid acquisitions by Lilly constituted and still constitute violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Chicago Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act and the Clayton Act; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, and having duly considered the comments filed thereafter by interested persons pursuant to Section 2.34, now in further conformity with the procedure prescribed in Section 2.34 of its

Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Eli Lilly and Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of Indiana, with its principal executive offices located at 307 East McCarty St., Indianapolis, Indiana.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

I

DEFINITIONS

It is ordered, That the following definitions shall apply in this order:

1. "Lilly" means respondent Eli Lilly and Company, its subsidiaries, and its successors and assigns.

2. "Animal Insulin Products" means insulin extracted from animal pancreas glands, including any and all stages of production (insulin salt cake, insulin crystals and/or finished insulin).

3. "Other Insulin Products" means insulin produced by chemical synthesis, by microbes genetically manipulated using recombinant DNA techniques, or by any other methods other than extraction from animal pancreas glands.

4. "Existing Patents" means:

(a) United States and foreign patents owned by Lilly, or with respect to which Lilly has the power to grant licenses or sub-licenses, as of the date that the agreement containing this order is signed by Lilly, and

(b) Applications for United States and foreign patents, and any patents which may issue on any such applications, which applications are owned by Lilly, or with respect to which Lilly has the power to grant licenses or sub-licenses, as of the date that the agreement containing this order is signed by Lilly.

5. "Existing Know-How" means technical information, processes and procedures, whether patented or unpatented, which are used by Lilly in commercial production of Animal Insulin Products within the United States as of the date that the agreement containing this order is signed by Lilly. Lilly's obligation to make certain of such know-how available to licensees pursuant to this order may be met by (a) providing such licensees with a written description of the licensed

know-how sufficient to enable one reasonably skilled in the art to understand and reproduce such know-how, and (b) upon written request by a licensee, additionally providing written clarification respecting licensed know-how to such licensee where such clarification is reasonably necessary.

6. "Future Patents" means United States patents (exclusive of Existing Patents) issued within five (5) years after the date that the agreement containing this order is signed by Lilly, which patents are owned by Lilly, or with respect to which Lilly acquires the power to grant licenses or sub-licenses.

7. "Future Know-How" means technical information, processes and procedures (exclusive of Existing Know-How), whether patented or unpatented and including any United States patents which may issue thereon, which relate to the production of Animal or Other Insulin Products, and which Lilly acquires from persons, research groups or companies other than Lilly and Lilly employees within five (5) years after the date that the agreement containing this order is signed by Lilly, and which are in writing and are known by Lilly to have been reduced to practice by Lilly or by the persons, research groups or companies from which the know-how is acquired. Lilly's obligation to make certain of such know-how available to licensees pursuant to this order may be met by (a) providing such licensees with a written description of the licensed know-how sufficient to enable one reasonably skilled in the art to understand and reproduce such know-how, and (b) upon written request by a licensee, additionally providing written clarification respecting licensed know-how to such licensee where such clarification is reasonably necessary.

8. "Patents Issuing on Future Applications" means United States patents (exclusive of Existing or Future Patents) owned by Lilly which issue on applications filed within five (5) years after the date that agreement containing this order is signed by Lilly, which applications cover innovations developed by Lilly or Lilly employees.

9. "Reduced to practice" means demonstrated by actual use, by tests or by laboratory experiments as being workable for its intended purpose.

10. "Domestic Company" means any sole proprietorship, partnership, corporation or other business entity that is a United States citizen and that is not owned or controlled by a business entity that is not a United States citizen.

11. "Foreign Company" means any sole proprietorship, partnership, corporation or other business entity that is not a United States citizen, and any business entity that is a United States citizen but is

owned or controlled by a business entity that is not a United States citizen.

12. "United States" means the United States of America, its territories and possessions, and the Commonwealth of Puerto Rico.

13. "The date that the agreement containing this order is signed by Lilly" means and is: May 30, 1979.

II

PRACTICES PROHIBITED

It is further ordered, That Lilly, and its directors, officers, agents, representatives and employees, directly or indirectly, or through any corporation, subsidiary, division or other device:

A. In connection with the purchase or sale of animal pancreas glands used in the manufacture of Animal Insulin Products:

(1) Shall not participate in any agreement or conspiracy with any manufacturer of any Animal Insulin Products or any buyer, broker or collector of animal pancreas glands to allocate or control the meat slaughterhouses within the United States from which animal pancreas glands are or will be obtained.

(2) Shall not participate in any agreement or conspiracy with any manufacturer of any Animal Insulin Products or any buyer, broker or collector of animal pancreas glands to allocate or divide animal pancreas glands obtained from meat slaughterhouses within the United States.

(3) Shall not participate in any agreement or conspiracy with any manufacturer of any Animal Insulin Products or any buyer, broker or collector of animal pancreas glands to suppress or limit actual or potential competition in the purchase or sale of animal pancreas glands obtained from meat slaughterhouses within the United States by (a) refusing to deal with any buyer, broker or collector of animal pancreas glands collected within the United States, or (b) inducing any manufacturer of any Animal Insulin Products, any buyer, broker or collector of animal pancreas glands or any meat slaughterhouses located within the United States, to refuse to deal with any buyer, broker or collector of animal pancreas glands collected within the United States.

(4) Provided that nothing contained in Subparagraphs (1), (2), and (3) above shall be construed to prevent Lilly (a) from making purchases of animal pancreas glands in the ordinary course of business from meat slaughterhouses, collectors, brokers and other sellers of such glands

