similar products in commerce, as "commerce" is defined in the Clayton Act, do forthwith cease and desist from:

(1) Knowingly inducing, or knowingly receiving or accepting, any discrimination in the price of such products by directly or indirectly inducing, receiving or accepting from any seller a net price respondents know or should know is below the net price at which said products of like grade and quality are being sold by such seller to other customers who in fact compete with respondents in the resale and distribution of such products.

(2) Maintaining, operating, or utilizing respondent National Parts Warehouse or any other organization as a means or instrumentality to induce or receive discounts or rebates which result in a net price respondents know or should know is below the net price at which said products of like grade and quality are being sold by such seller to other customers who in fact compete with respondents in the resale and distribution of such products. The provisions of this paragraph (2) are not applicable to respondent National Parts Warehouse or respondent Bryant M. Smith, Sr.

For the purpose of determining the "net price" under the terms of this order, there shall be taken into account all discounts, rebates, allowances, deductions or other terms and conditions of sale by which net prices are effected.

It is further ordered, That the aforesaid respondents shall, within sixty (60) days after service upon them of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with the order to cease and desist.

By the Commission, Commissioner Elman not concurring and Commissioner Higginbotham concurring.

IN THE MATTER OF

AMERICAN CYANAMID CO. ET AL.

ORDER, ETC., IN REGARD TO THE ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION ACT

Docket 7211. Complaint, July 28, 1958—Decision, Dec. 17, 1963

Final order modifying desist order of August 8, 1963, page 1895 herein requiring six antibiotic manufacturers and distributors accounting for 100% of the industry's sale of tetracycline, to cease concerted price fixing and collusive

bidding in the sale of that product—by (1) deleting from paragraph 1 the words "knowingly common course of action"; (2) changing paragraphs 1 and 2 so as to apply to "tetracycline sold in dosage forms for human consumption"; (3) inserting a proviso which would allow respondents to use fair trade agreements pursuant to the McGuire Act; and (4) adding a proviso to paragraph 2 to allow respondents opportunity to take advantage of price changes made before the effective date of the order and not in the record; and

Adding the requirements that Pfizer grant a non-exclusive, non-discriminatory license to any domestic applicant to make tetracycline under all claims of its patent obtained by unfair means, that American Cyanamid grant a similar license to any domestic applicant to make chlortetracycline for conversion into tetracycline, and that both furnish to licensees all necessary information, know-how and cultures for such manufacture; and requiring that any assignee or purchaser of the patents concerned observe the provisions of the instant order.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (38 Stat. 717, 15 U.S.C.A. Sec. 41, 52 Stat. 111), and by virtue of the authority vested in it by said Act, the Federal Trade Commission having reason to believe that American Cyanamid Company, a corporation; Bristol-Myers Company, a corporation; Bristol Laboratories Inc., a corporation; Chas. Pfizer & Co., Inc., a corporation; Olin Mathieson Chemical Corporation, a corporation; and The Upjohn Company, a corporation, more particularly described and referred to hereinafter as respondents, have violated the provisions of Section 5 of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby names the previously mentioned corporations, each and all as respondents herein, and issues its complaint against each of the named parties stating its charges in that respect as follows:

PARAGRAPH 1. Respondent American Cyanamid Company, hereinafter referred to as Cyanamid, is a corporation organized and existing under the laws of the State of Maine, with its principal office and place of business located at 30 Rockefeller Plaza, New York 20, New York.

Respondent Bristol-Myers Company is a corporation organized and existing under the laws of the State of Delaware, with its principal office and place of business located at 630 Fifth Avenue, New York, New York

Respondent Bristol Laboratories Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal office and place of business located at Syracuse, New York. Re-

spondents Bristol-Myers Company and Bristol Laboratories Inc. are hereinafter jointly referred to as Bristol unless otherwise indicated.

Respondent Chas. Pfizer & Co., Inc., hereinafter referred to as Pfizer, is a corporation organized and existing under the laws of the State of Delaware, with its principal office and place of business located at 11 Bartlett Street, Brooklyn 6, New York.

Respondent Olin Mathieson Chemical Corporation, hereinafter referred to as Olin Mathieson, is a corporation organized and existing under the laws of the State of Virginia, with its principal office and place of business located at 460 Park Avenue, New York 22, New York.

Respondent The Upjohn Company, hereinafter referred to as Upjohn, is a corporation organized and existing under the laws of the State of Michigan, with its principal office and place of business located at 301 Henrietta Street, Kalamazoo, Michigan.

PAR. 2. The respondents hereinbefore named and described, either directly or through operating divisions or subsidiaries, are engaged in the manufacture, sale and distribution, or the sale and distribution of antibiotics, antibiotic substances and antibiotic products hereinafter referred to as antibiotics.

Each of the respondents is engaged in the business of selling and distributing antibiotics to customers located in States other than the State in which each respondent respectively maintains production or processing facilities and in some instances to customers located outside the continental limits of the United States. There has been and is now a pattern and course of interstate commerce in said antibiotics by respondents within the intent and meaning of the Federal Trade Commission Act.

PAR. 3. Each of the respondents is in substantial competition with each and all of the other respondents named herein and with other members of the antibiotics industry in the manufacture, sale, processing and distribution of antibiotics in interstate commerce, except to the extent that competition has been hindered, lessened, restricted and eliminated by the unfair methods of competition and unfair acts and practices hereinafter set forth.

PAR. 4. Antibiotics are substances produced by certain microorganisms and have the capacity to inhibit the growth of infectious and disease producing microorganisms and destroy them. Among the antibiotics manufactured or distributed by the respondents herein, and those with which this complaint is primarily concerned, are those popularly known as "wonder drugs" because of their rapid action,

life-saving qualities and abilities to counteract effectively and cure a broad variety of illnesses and diseases.

Antibiotics are among the most recent and most effective weapons against infection and infectious diseases caused by microorganisms such as the gram-positive bacteria, gram-negative bacteria, acid-fast bacteria, the rickettsiae, certain spirochetes, large viruses and certain protozoa. Among the diseases which respond to antibiotics therapy are: pneumonia, mastoiditis, syphilis, gonorrhea, typhoid fever, meningitis, peritonitis, typhus, bacterial endocarditis, tuberculosis, plague, streptococcal sore throat, rocky mountain spotted fever, and many others. Antibiotics are effective in preventing and controlling secondary infections in measles, influenza, and in other diseases not directly responsive to antibiotic therapy. Antibiotics are also employed prophylactically to prevent infection or disease as, for example, prior to surgery, and to prevent recurrences of infection and disease as in the case of rheumatic fever. Antibiotics are, therefore, of vital and unique importance to the health and welfare of the general public.

PAR. 5. From its inception with the discovery of penicillin in the era prior to World War II, the modern antibiotics industry has been characterized by dynamic growth and phenomenal sales. The industry sales are presently in excess of $330 million per year with tetracycline being the largest selling antibiotic by dollar volume.

Antibiotics are sold by each of these respondents to wholesalers, retailers, hospitals, sanitariums, government institutions, dispensaries, and sometimes to physicians. The respondents herein account for 100% of the industry's sales of tetracycline and domestic sales of this one antibiotic alone exceeded $100 million in 1957.

Each of the respondents sells its antibiotics, among other products, under a number of brand names. Among the antibiotics sold and brand names utilized, respectively, by the respondents are the following:

Cyanamid, through its Lederle Laboratories Division, manufactures and sells chlortetracycline, marketed under the trade name, among others, of Aureomycin; and tetracycline marketed under the trade names, among others, of Achromycin, Achromycin V, Archrostatin, and Achrocidin.

Bristol-Myers Company, through its subsidiary Bristol Laboratories Inc., manufactures and sells tetracycline, marketed under the trade names, among others, of Polycycline and Tetrex.

Pfizer manufactures and sells oxytetracycline, marketed under the trade names, among others, of Terramycin, Terrabon, and Terra-cortril; and tetracycline marketed under the trade names, among others,

of Tetracyn, Tetracyn V, Tetrabon, Tetrabon V, Tetracydin, Sigmamycin and Signemycin.

Olin Mathieson Chemical Corporation, through its E.R. Squibb & Sons Division, is engaged in the sale and distribution of tetracycline, marketed under the trade names, among others, of Steclin, Mysteclin, Mysteclin V, and Sumycin.

Upjohn is engaged in the sale and distribution of tetracycline marketed under the brand names, among others, of Panmycin, Panmycin Phosphate, Comycin and Panalba.

PAR. 6. The ownership of United States letters patent on antibiotics is of critical importance within the industry. A valid patent confers an exclusive right to manufacture and sell and the right to license others to manufacture and sell and the right to license others to manufacture and sell a particular antibiotic or antibiotic product. Through ownership of a valid patent the patentee may prevent competition by other companies in the manufacture and sale of the patented product.

On September 13, 1949, Cyanamid was granted United States Letters Patent No. 2,482,055 on chlortetracycline (Aureomycin). No other company was licensed to produce or sell this antibiotic in the United States until 1954 when Pfizer received a license to manufacture chlortetracycline for the purpose of extracting tetracycline therefrom. Pfizer agreed to pay a 2½% royalty to Cyanamid on the former's sales of tetracycline under said license. Thereafter, in 1955, Bristol was licensed by Cyanamid to produce up to 6% chlortetracycline in the production of tetracycline and to sell tetracycline products containing not more than 6% chlortetracycline. Bristol agreed to pay a 5% royalty to Cyanamid on Bristol's sales of tetracycline under said license. At the same time Bristol granted Cyanamid rights to manufacture and sell tetracycline under any tetracycline patents which might issue to Bristol as a result of applications then on file with the United States Patent Office.

On July 18, 1950, Pfizer was granted United States Letters Patent No. 2,516,080 on oxytetracycline (Terramycin). No other company has been licensed to manufacture or sell this antibiotic in the United States.

On January 11, 1955, Pfizer was granted United States Letters Patent No. 2,699,054 on tetracycline. Under prior arrangements Pfizer issued a license to Cyanamid to also manufacture and sell this newly patented antibiotic. Cyanamid agreed to pay a 2½% royalty to Pfizer on all of Cyanamid's sales of tetracycline. Later, during March 1956, a license to manufacture and sell tetracycline was granted

to Bristol Laboratories Inc. by Pfizer with Bristol agreeing to pay a 3½% royalty to Pfizer on all of Bristol's sales of tetracycline, and a license to sell tetracycline was granted Olin Mathieson and Upjohn. The Pfizer license to Cyanamid was agreed upon at the time Cyanamid licensed Pfizer under the chlortetracycline patent. The Pfizer licenses to Bristol, Olin Mathieson and Upjohn followed settlement of litigation between Pfizer and the licensed companies.

Chlortetracycline (Aureomycin), oxytetracycline (Terramycin) and tetracycline, which are marketed in identical dosage forms by the various respondents, are sometimes referred to as the "tetracyclines" and are characterized in the industry as "broad spectrum" antibiotics because of their wide range of effectiveness against both gram-positive and gram-negative microorganisms.

PAR. 7. Respondent Pfizer has in the past and is now engaging in unfair methods of competition and unfair acts and practices in commerce, in connection with the production and sale of antibiotics in that Pfizer has done and performed the following acts and practices:

(a) Unreasonably foreclosed access to substantial markets to competitors and potential competitors;

(b) Denied to competitors and potential competitors a reasonable opportunity to compete;

(c) Attempted to monopolize the antibiotics industry;

(d) Attempted to monopolize and has monopolized the tetracycline industry;

(e) Made false, misleading and incorrect statements to the United States Patent Office with the purpose and effect of inducing the United States Letters Patent No. 2,699,054;

(f) Caused United States Letters Patent No. 2,699,054 to be issued as a result of misrepresentations advanced by Pfizer on behalf of the applicant for the patent;

(g) Caused United States Letters Patent No. 2,699,054 to issue where there was no real novelty or invention in the claims of said patent;

(h) Caused United States Letters Patent No. 2,699,054 to issue although the claims of said patent disclose no patentable invention in view of the prior state of the art at the time the application was filed;

(i) Caused United States Letters Patent No. 2,699,054 to issue although the alleged invention was made known or used by others in this country before the alleged invention by the applicant for said patent;

(j) Caused United States Letters Patent No. 2,699,054 to issue although the alleged invention was in public use or on sale in this country more than one year prior to the filing of the application for said patent;

(k) Caused United States Letter Patent No. 2,699,054 to issue although no invention was required to devise and perfect the subject matter of the patent in view of the state of the art prior to the alleged invention;

(l) Caused United States Letters Patent No. 2,699,054 to issue although the subject matter of the patent was obvious at the time of filing the application for the patent to anyone having ordinary skill in the art to which the subject of the patent pertains;

(m) Issued invalid licenses under United States Letters Patent No. 2,699,054.

PAR. 8. The acts and practices of the respondent Pfizer, as herein alleged, have had and do have the effect of hindering, lessening, restricting, restraining and eliminating competition in the sale of antibotics; have had and do have a dangerous tendency to unduly hinder competition or to create in respondent a monopoly; have constituted an attempt to monopolize and have foreclosed markets and access to markets to competitors in the sale and distribution of antibiotics; are all to the prejudice of competitors of respondent and to the public; and constitute each and all unfair methods of competition and unfair acts and practices in commerce within the intent and meaning of the Federal Trade Commission Act.

PAR. 9. For many years, and continuing to the present time, each and all of the respondents named herein have engaged in unfair methods of competition and unfair acts and practices in commerce in the manufacture, sale and distribution of tetracycline, chlortetracycline and oxytetracycline in that they have, through conspiracy, combination, agreement, and planned common courses of action, and as a part thereof, done and performed the following:

(a) Fixed and maintained arbitrary, artificial, non-competitive and rigid prices;

(b) Fixed prices;

(c) Fixed and maintained prices, terms and conditions of sale;

(d) Policed and enforced the illegally fixed prices;

(e) Established and maintained illegal resale price maintenance agreements;

(f) Established and maintained agreements to license and cross license, and established and maintained licenses and cross licenses under patents with the purpose and effect of unreasonably foreclosing

and preventing competition in the production and sale of tetracycline and chlortetracycline;

(g) Unreasonably foreclosed access to substantial markets to competitors and potential competitors;

(h) Denied to competitors and potential competitors a reasonable opportunity to compete;

(i) Attempted to monopolize the antibiotics industry;

(j) Attempted to monopolize and have monopolized the manufacture, sale and distribution of tetracycline;

(k) Pfizer, Bristol and Cyanamid withheld from the United States Patent Office material and probative information and material in connection with the filing and prosecution of patent applications, as a result of which Pfizer was enabled to procure United States Letters Patent No. 2,699,054 on tetracycline;

(l) Pfizer submitted false, misleading and incorrect information and material to the United States Patent Office in connection with the filing and prosecution of patent applications, as a result of which Pfizer was enabled to procure United States Letters Patent No. 2,699,054;

(m) Cyanamid, Bristol, Olin Mathieson and Upjohn solicited and accepted and Pfizer issued licenses under United States Letters Patent No. 2,699,054 with knowledge that:

1. Material and probative information and material were withheld from the United States Patent Office by one or more of the applicants for said patent prior to, during and after interference proceedings before the United States Patent Office.

2. Pfizer submitted false, misleading and incorrect information to the United States Patent Office in support of its application for said patent.

3. There was no real invention or novelty in the claims of said patent.

4. The claims of said patent disclosed no patentable invention in view of the prior state of the art at the time the initial application therefor was filed.

5. The alleged invention was made known or used by others in this country before the alleged invention by the applicant (Conover).

6. The alleged invention was in public use and/or on sale in this country more than one year prior to the filing of the application for said patent.

7. The subject of the patent was obvious, at the time of the filing of the respective applications for the patent, to anyone having ordinary skill in the art.

PAR. 10. The acts and practices of the respondents, as herein alleged, have had and do have the effect of hindering, lessening, restricting, restraining and eliminating competition in the sale of antibiotics; have had and do have a dangerous tendency to unduly hinder competition or to create in respondents a monopoly; have constituted an attempt to monopolize; have foreclosed markets and access to markets to competitors in the sale and distribution of antibiotics; are all to the prejudice of competitors of respondents and to the public; and constitute unfair methods of competition and unfair acts and practices in commerce within the intent and meaning of the Federal Trade Commission Act.

FINDINGS AS TO THE FACTS AND CONCLUSIONS OF LAW

AUGUST 8, 1963

Pursuant to the provisions of the Federal Trade Commission Act, the Federal Trade Commission, on July 28, 1958, issued and subsequently served its complaint in this proceeding, charging said respondents with the use of unfair methods of competition in commerce and unfair and deceptive acts and practices in commerce in the sale of antibiotics, in violation of the provisions of the Federal Trade Commission Act. After the issuance of said complaint and the filing of respondents' answers thereto, hearings were held before duly designated hearing examiners of the Commission and testimony and other evidence in support of and in opposition to the allegations of said complaint were received into the record. In an initial decision filed October 31, 1961, the hearing examiner found that the charges 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, and issues its own order, all of which, together with the accompanying opinion, shall be in lieu of the findings, conclusions and order contained in the initial decision.

FINDINGS AS TO THE FACTS

1. Respondent American Cyanamid Company, hereinafter sometimes referred to as Cyanamid, is a corporation organized and existing under the laws of the State of Maine, with its principal office

and place of business located at 30 Rockefeller Plaza, New York 20, New York.

Respondent Bristol-Myers Company is a corporation organized and existing under the laws of the State of Delaware, with its principal office and place of business located at 630 Fifth Avenue, New York, New York.

Respondent Bristol Laboratories Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal office and place of business located at Syracuse, New York. Respondents Bristol-Myers Company and Bristol Laboratories Inc. are hereinafter jointly referred to as Bristol unless otherwise indicated.

Chas. Pfizer & Co., Inc., hereinafter sometimes referred to as Pfizer, is a corporation organized and existing under the laws of the State of Delaware, with its principal office and place of business located at 11 Bartlett Street, Brooklyn 6, New York.

Respondent Olin Mathieson Chemical Corporation, hereinafter sometimes referred to as Squibb, is a corporation organized and existing under the laws of the State of Virginia, with its principal office and place of business located at 460 Park Avenue, New York 22, New York.

Respondent Upjohn Company, hereinafter sometimes referred to as Upjohn, is a corporation organized and existing under the laws of the State of Michigan, with its principal office and place of business located at 301 Henrietta Street, Kalamazoo, Michigan.

2. Respondents, either directly or through operating divisions or subsidiaries, are engaged, among other things, in the manufacture, sale and distribution, or the sale and distribution, of antibiotics, antibiotic substances and antibiotic products. Each respondent sells its antibiotics, among other products, under a number of brand names. Among the antibiotics sold and brand names utilized by respondents, are the following:

Cyanamid, through its Lederle Laboratories Division, manufactures and sells chlortetracycline, marketed under the trade name of Aureomycin; and tetracycline, marketed under the trade names, among others, of Achromycin, Achromycin V, Achrostatin, and Achrocidin.

Bristol manufactures and sells tetracycline, marketed under the trade names, among others, of Polycycline and Tetrex.

Pfizer manufactures and sells oxytetracycline, marketed under the trade name of Terramycin; and tetracycline, marketed under the trade names, among others, of Tetracyn, Tetracyn V, Tetrabon, Tetrabon V. Tetracydin, and Sigmamycin and Signemycin.

Squibb is engaged in the sale and distribution of tetracycline, marketed under the trade names, among others of Steclin, Mysteclin V, and Sumycin.

Upjohn is engaged in the sale and distribution of tetracycline, marketed under the trade names, among others, of Panmycin, Panmycin Phosphate, Comycin and Panalba.

3. Each respondent sells and distributes antibiotics, including tetracycline, to customers located in states other than the state in which each respondent, respectively, maintains production or processing facilities, and in some instances to customers located outside the United States. Each has been and is now engaged in interstate commerce in the sale and distribution of its antibiotics within the intent and meaning of the Federal Trade Commission Act. To the extent that competition has not been restrained, lessened, or destroyed as a result of unlawful understandings, agreements, combinations, or conspiracies or other unfair methods of competition hereinafter found to exist, said respondents are in competition with each other in the sale and distribution of their respective products.

4. Antibiotics are chemical substances produced by certain microorganisms and have the capacity to destroy and inhibit the growth of infectious and disease-producing microorganisms. The earlier antibotics such as penicillin and streptomycin are known as narrow spectrum antibiotics because they are normally effective against either gram-positive or gram-negative bacteria but not both. The antibiotics with which this case is concerned are known beginning with the discovery of Aureomycin, as broad spectrum antibiotics because they are effective against a far wider range of bacteria, including both gram-positive and gram-negative bacteria. Because of their wide-range of efficacy against practically all infectious diseases, the broad spectrum antibiotics have become known popularly as "wonder drugs". Their use results in a marked decrease in the cost of treating those diseases, and they presently are prescribed in substantially all instances in which they are effective. Antibiotics are also employed to prevent infection or disease as, for example, prior to surgery, and to prevent recurrences of infection and disease. Antibiotics are, therefore, of vital and unique importance to the health and welfare of the general public.

Antibiotics, including tetracycline, Aureomycin and Terramycin, as all ethical drugs, are products which can be obtained by the ultimate consumer or patient only under the authority of a doctor's perscription. Each is customarily prescribed by the physician under the respective brand name of the manufacturer, rather than its generic

or chemical name. It is the physician's prescription which determines the amount and brand of drug which the pharmacist will sell. Consequently, respondents direct a major portion of their sales and promotional efforts at physicians, emphasizing their respective trade names. By law and custom, pharmacists are prohibited from substituting one brand of an ethical drug for another without permission of the physician.

Aureomycin, Terramycin and tetracycline are produced by the fermentation of microorganisms in aqueous nutrient media. The medium is inoculated with the microorganism, and under controlled and aseptic conditions the microorganism is allowed to grow. After a period of time judged to be optimum for antibiotic yield, the fermentation is stopped and the antibiotics are recovered from the broth. The particular strain of microorganism used will cause variations in yield. Various strains will work best with slightly different media, and it is often within the ability of the person skilled in this art to make minor variations in the media and the fermentation to provide each strain with the particular conditions under which it will be found to thrive most satisfactorily. For production on a commercial scale, the fermentation is conducted in large vats and the antibiotic substance is recovered and subjected to purification procedures in order to arrive at a product suitable for therapeutic use. The product is then processed and packaged in various dosage forms. Sometimes the product is combined with other therapeutic products.

The yield of antibiotic content per milliliter of fermentation broth is commonly called "potency." Potency is usually stated in micrograms per milliliter. Potency is measured by a number of means, including biological assays and chemical assays. In ascertaining the potency of an antibiotic broth or amorphous product of unknown ingredients recovered from a broth, an assumption must be made initially as to which antibiotic is present and the potency is then stated in micrograms per milliliter in terms of that antibiotic.

Aureomycin is made by the fermentation of a species of microorganism known as *Streptomyces aureofaciens*, hereinafter referred to as *S. aureofaciens.*

Tetracycline can also be produced by subjecting Aureomycin to a process of mild catalytic hydrogenation, which removes the chlorine atom from the Aureomycin molecule. This chemical transformation was the original method by which tetracycline was discovered.

5. The patent covering Aureomycin is the Duggar patent, U.S. Patent 2,482,055, issued September 13, 1949. (The Niedercorn patent, U.S. Patent 2,609,329, issued September 2, 1952, is an improvement pa-

tent on a process for producing Aureomycin.) Both are owned by Cyanamid. The Sobin patent, U.S. Patent 2,516,080, covering the product Terramycin, was issued to Pfizer on July 18, 1950; the Conover patent, U.S. Patent 2,699,054, covering tetracycline, was issued to Pfizer on January 11, 1955.

No company has been licensed by Cyanamid to sell Aureomycin in the United States. Pfizer has been licensed to manufacture Aureomycin for the limited purpose of converting it to tetracycline, and Bristol has been licensed to produce up to 6% Aureomycin in the production of tetracycline, and to sell tetracycline containing not more than 6% Aureomycin. Pfizer has licensed no company to produce or sell Terramycin. As a result of their patents, Cyanamid and Pfizer have had a legal monopoly of the production and sale of Aureomycin and Terramycin, respectively. Pfizer has licensed Cyanamid and Bristol to manufacture and sell tetracycline, and has licensed Squibb and Upjohn to sell tetracycline.

6. The extent of competition between specific antibiotics depends upon the degree of susceptibility, if any, of the disease-causing organisms to the particular antibiotic, the extent to which the medical profession may prefer one antibiotic to another antibiotic, either from a therapeutic standpoint or from ease and convenience of administration, the prevalence of undesirable side effects, such as toxicity, the physician's knowledge and opinion of the particular product and brand, and price — where antibiotics are substantially interchangeable medically.

Tetracycline, Aureomycin and Terramycin are broad spectrum antibiotics which have, with some exceptions, the same anti-bacterial effectiveness and therefore can be used by the medical profession for the treatment and cure of the same general range of diseases. They are, therefore, to that extent in substantial competition with one another. Tetracycline is definitely superior to Aureomycin with respect to therapeutic qualities other than anti-bacterial effectiveness. In many instances, in hospitals, tetracycline has become the drug of choice among the broad spectrum antibiotics.

7. Prior to 1952, the chemical structures of Aureomycin and Terramycin were unknown. During the spring of that year, a Pfizer research team headed by Dr. R. B. Woodward of Harvard University, discovered the molecular structure of these two antibiotics. A member of the research team, Dr. Conover, noting the similarity in the structures of the two antibiotics, speculated that it might be possible to develop a new antibiotic by removing the chlorine atom from Aureomycin. By subjecting Aureomycin to mild hydrogenation by

means of a catalyst such as palladium Conover removed the chlorine atom and, in June of 1952, produced tetracycline.

On August 8, 1952, an article by the Pfizer research team was submitted to the *Journal of the American Chemical Society* disclosing the formations and structures of Aureomycin, Terramycin and tetracycline. This article, referred to hereinafter as the Stephens article, was published in the *Journal* on October 5, 1952.

On October 23, 1952, Conover filed an application for a patent claiming the product deschloroaureomycin (later called tetracycline), its salts, and a process for producing it by hydrogenation of Aureomycin. On July 23, 1953, the Patent Office rejected the Conover application on the ground that the subject matter was obvious in the light of the Aureomycin (Duggar) and Terramycin (Sobin) patents, because of the similarity of the structural formulae of the three antibiotics.

On October 20, 1953, Pfizer filed a preliminary amendment to its patent application pointing out that the structures of Aureomycin and Terramycin were not known at the time of Conover's discovery of tetracycline. Thereafter, the patent examiner withdrew the rejection of the application on the aforementioned ground.

In 1948, Cyanamid had hydrogenated Aureomycin and obtained a product which it later claimed was tetracycline. In December 1952, Cyanamid repeated its 1948 work and embarked upon a project in which tetracycline was produced from Aureomycin by hydrogenation. On March 16, 1953, Cyanamid filed its Boothe-Morton application for a patent on tetracycline, its salts, and a process for manufacturing it by hydrogenating Aureomycin.

On August 6, 1953, Cyanamid submitted an article to the *Journal of the American Chemical Society* describing the production of tetracycline by deschlorination of Aureomycin. On August 13, 1953, Pfizer submitted a similar article to the *Journal*. Both articles were published in the Journal on September 20, 1953. The disclosure of tetracycline and the process of deschlorination made possible the testing of previously unknown and unrecognized antibiotics, using the revealed tetracycline as a basis for comparison.

8. By Fall of 1953, Cyanamid had already determined from clinical tests of tetracycline that this product was superior to Aureomycin and had decided to promote tetracycline as its principal antibiotic. Pfizer knew of these clinical tests and was reasonably certain that Cyanamid would market tetracycline. At this time, Cyanamid and Pfizer dominated the broad spectrum antibiotic market. In 1953, they accounted for over 90% of the total volume of sales of such products. The bal-

ance of the market share was held by Parke Davis and Company, which produced and sold the third broad spectrum antibiotic, Chloromycetin. Both Aureomycin and Terramycin were patented, and neither Cyanamid nor Pfizer had ever granted a license under its patent or had sold its product in bulk to any other drug producer or distributor. The prices of these two antibiotics had been virtually identical since 1951.

Both Cyanamid and Pfizer knew that tetracycline, if produced and sold commercially, would be fully competitive with Aureomycin and Terramycin. They both knew or had reason to believe that the value of their respective patents and their dominant positions in the broad spectrum antibiotic market would be impaired by the unrestricted production and sale of tetracycline by other firms. Moreover, they knew or had reason to believe that if tetracycline could be sold by other firms in free and open competition, the price of this product as well as that of other broad spectrum antibiotics would be forced downward as the price of penicillin had been in recent years. In this connection, during and subsequent to World War II, many companies had entered the penicillin industry and price wars broke out. The price of penicillin had declined repeatedly and the market for this product became highly volatile, characterized by low prices, uncertain profits, substantial losses, and attrition among producers. As one Cyanamid official testified with respect to the effect of unrestricted competition in the sale of penicillin and the probable effects of such competition in the sale of tetracycline:

> Lederle itself had to go out of the penicillin business because the price was cut so low. I had fairly good reason as a matter of common sense to believe that would happen here. (Tr. 5953.)

Even after Pfizer had reason to believe that the production and sale of tetracycline would be controlled by patent, officials of that company advised a group of security analysts that the price of this product would trend downward because of competition but that they did not anticipate anything similar to the penicillin price deterioration.

9. As hereinbefore stated, both Pfizer and Cyanamid had filed applications for patents on the product tetracycline and the deschlorination process for its manufacture. Both firms were, of course, aware that tetracycline could not be made by this process without infringing Cyanamid's Duggar patent on the product Aureomycin. On Septemper 25, 1953, the Heyden Chemical Corporation announced it had discovered an antibiotic, designated HA–20A, which might be tetracycline and that this antibiotic could be produced by direct fermentation. This announcement was the subject of an article which

appeared in the *Journal of Commerce* on October 1, 1953. On September 28, 1953, Heyden applied for a patent (the Minieri application) on HA–20A, its salts, and a process for production thereof by fermentation using a newly discovered strain of *S. aureofaciens* and a mutant thereof. On October 6, 1953, Upjohn contacted Heyden with a view to purchasing bulk tetracycline from Heyden and marketing it, but no agreement was reached between these two firms.

Within about two days after the public announcement of the aforementioned discovery of tetracycline by the fermentation process, Cyanamid and Heyden entered into negotiations for the purchase of the latter's Antibiotic Division and on November 4, 1953, Cyanamid acquired this division, including the rights to the Minieri tetracycline patent application. On October 14, 1953, two weeks after the aforementioned announcement by Heyden, Cyanamid filed an application for a patent (the Martin-Bohonos application) claiming direct fermentation processes for producing tetracycline.

Heyden's Antibiotic Division had been engaged in the bulk sale of penicillin and streptomycin and had been sustaining substantial losses on penicillin in the two years preceding its acquisition by Cyanamid because of the price decline and overproduction of this product. In the previous year Cyanamid's own sales of penicillin dropped two million dollars as compared to 1951, and an official of that company stated that "the year experienced a panic in the penicillin field." A Bristol executive testified as follows with respect to the marketability of penicillin facilities in 1953:

> Q. You feel that drug companies in general were interested in acquiring antibiotic penicillin production facilities in the summer of 1953?
>
> A. I am of the opinion it would have been very difficult to sell Bristol's plant at a fraction of its value at that time. (Tr. 9062.)

Cyanamid itself had recently discontinued selling penicillin because of the price decline on this product. Cyanamid, however, purchased Heyden's antibiotic facilities at a price approximately $2.75 million in excess of an independent appraisal of such facilities.

Although the president of Cyanamid testified that Cyanamid was primarily interested in acquiring Heyden's modern plant and streptomycin and penicillin business, the Commission finds from all the aforementioned circumstances and subsequent events that one of Cyanamid's reasons for making this acquisition was to obtain the rights to the Minieri tetracycline patent application and to eliminate a potential competitor in the tetracycline market. (Cyanamid eventually obtained a patent on the direct fermentation process covered by this application.)

10. On November 9, 1953, Bristol issued a news release which stated in part as follows:

> **Last Friday in certain financial publications there appeared a story regarding the discovery by our research group of a new antibiotic, tetracycline, which is closely related to aureomycin and terramycin in structure. This story was not released by Bristol but came to the attention of the press through sources not in our control. It is unfortunate that this premature disclosure was made; it is especially so since you were not previously informed.**
>
> **However, we can confirm the fact that tetracycline has been produced at Bristol by a fermentation process and that Bristol has a number of patent applications in the field.**

An application for a patent on tetracycline and a process of producing it by fermentation was filed by Bristol on October 19, 1953 (the Heinemann application). Both product and process claims in this application were rejected by the Patent Office on December 8, 1953, on the ground that tetracycline had been coproduced with Aureomycin in the Duggar and Niedercorn fermentations. The product claims were also rejected on the ground that they had been anticipated by the Stephens article. Prior to this time, the patent examiner handling these applications had rejected the process claims in the Minieri application on the ground of coproduction of tetracycline in the Duggar fermentation process.

11. In November of 1953, Schwartz, the president of Bristol, visited Malcolm, then general manager of Cyanamid's Lederle Laboratories Division, in an attempt to secure an agreement with Cyanamid that the successful applicant for a tetracycline patent would license the other. Schwartz informed Malcolm that Bristol's fermentation process would not infringe the Aureomycin patent and did not offer to pay a royalty to Cyanamid for a license under the latter's Aureomycin patents. Malcolm asked Schwartz if he would be interested in a license for the Bristol label only and Schwartz stated that he would not and indicated that Bristol was planning to sell tetracycline in bulk as well as under its own label. No agreement was reached at this meeting or during a later conversation between Schwartz and Malcolm.

Attempts were made by Schwartz during 1954 to secure a license agreement from Pfizer to manufacture and sell tetracycline in bulk in the event Pfizer obtained a patent on this product. Schwartz was at first informed by McKeen, president of Pfizer, that Pfizer did not intend to license any company (other than Cyanamid) to produce tetracycline. At a later date, an official of Pfizer wanted to know whether Bristol would sell tetracycline in bulk to Wyeth and Squibb and referred to these firms as "the two worst price cutters in the

business." This same official subsequently advised Schwartz that he could offer Bristol a license to sell under its own label only. Schwartz refused this offer and also regarded as unsatisfactory the suggestion by the Pfizer official that Bristol take one bulk customer such as Parke, Davis and sell some bulk to Pfizer.

12. On October 29, 1953, the patent examiner handling the Cyanamid and Pfizer patent applications issued a notice to copy claims on tetracycline to Boothe-Morton (Cyanamid) and Conover (Pfizer), thereby indicating an intention to declare an interference between these two applicants. Under Patent Office rules, an interference is a proceeding conducted for the purpose of determining priority between two or more applicants claiming the same invention.

Having reason to believe that Cyanamid was the other party to the interference, McKeen of Pfizer visited Malcolm of Cyanamid at the latter's office on or about November 7, 1953; and on or about November 15, 1953, he made a second visit to Malcolm's office. According to McKeen's testimony, the purpose of these visits was to discuss a settlement of the interference. Both Cyanamid and Pfizer claim that a "blocking" situation would have existed if Pfizer received a patent on tetracycline, since Cyanamid's Aureomycin patent would prevent Pfizer from making tetracycline and Cyanamid, of course, would be unable to make tetracycline without infringing Pfizer's tetracycline patent Although both McKeen and Malcolm knew that Cyanamid could block Pfizer from making tetracycline by the deschlorination process, neither of them knew whether or not tetracycline could be made by some other process which would not infringe the Aureomycin patents. As a matter of fact, they had reason to believe that tetracycline could be produced without infringing Cyanamid's patents. McKeen testified that at the time of his conversations with Malcolm, Pfizer hoped to produce tetracycline by a method other than deschlorination. Both Malcolm and McKeen knew at that time that tetracycline could be produced by direct fermentation and Malcolm had been advised by Schwartz that Bristol could produce tetracycline by its fermentation process without infringing the Aureomycin patents. Even after Bristol began to sell tetracycline in April 1954, Cyanamid did not know whether its patents were being infringed. According to the testimony of a Cyanamid official, one of the reasons Cyanamid entered into a subsequent interference was to get information about Bristol's process in order to ascertain whether Bristol was infringing the Aureomycin patents. Malcolm, himself, admitted that it would be necessary to see Bristol's fermentation broth to determine whether Aureomycin was being produced.

McKeen and Malcolm did not know that either the product tetracycline or the process for its production was patentable at the time of these meetings. Under Patent Office rules of practice, the declaration of the interference on the process and product application filed by Cyanamid and Pfizer meant that the patent examiner had determined that the subject matter of the applications was patentable. Such a determination was merely a preliminary one, however, since, as both parties were fully aware, the patent examiner could later have changed his mind and ruled that the subject matter of the applications was unpatentable. In this connection, the aforesaid rules of practice expressly provide for the dissolution of an interference when the subject matter is found to be unpatentable.

13. In November 1953, the patent examiner asked Cyanamid's patent attorney, Edelblute, whether strains of the microorganism *S. aureofaciens*, used by Cyanamid in producing Aureomycin, may have produced tetracycline. On December 7, 1953, this patent attorney filed an amendment to the Boothe-Morton application which included the following remarks:

> While discussing this case, the Examiner asked whether or not strains of *S. aureofaciens* employed by applicant's assignee in the production of Aureomycin might have produced quantities of tetracycline. Recently, strains which do this have been isolated and under favorable and controlled conditions will produce tetracycline. However, in the laboratory of the applicant's assignee, the presence of tetracycline in the fermentation liquor or in the Aureomycin products that have been made and sold by them, has not been demonstrated. Obviously, the fermentation liquors that have been produced over the past years are no longer available and cannot now be examined. Some were examined, however, several years ago for antibiotics other than chortetracycline [sic] and no tetracycline was found. Some of the Aureomycin products that were produced several years ago by applicant's assignee also have been examined recently for tetracycline content and none of the latter was found. It seems therefore, that applicants and their assignee can unequivocally state that there has not been any tetracycline produced by them, inadvertently or otherwise, in their operations, with the exception of the materials specifically produced by the process of the present invention or by a fermentation process which forms the subject matter of patent applications of which the Examiner is undoubtedly aware.
>
> The fact that no tetracycline was produced under the conditions employed by applicant's assignee is not surprising since the production of this antibiotic is dependent upon the strain of microorganism that is used, the composition of the fermentation medium and other conditions. In fact, it is possible to grow strains of *S. aureofaciens* without producing chlortetracycline or other antibiotic material. The Examiner need, therefore, have no concern that the product tetracycline is not patentable at law to the present inventors. (CX 5, p.47.)

These remarks were erroneous since tetracycline is and always has been present in Aureomycin and is inherently produced in the processes of Duggar and Niedercorn

On February 25, 1954, Doctor Nestor Bohonos, the Cyanamid Director of Mycology Research, sent the following memorandum on the subject of "Old Aureomycin Samples for Chromotographic Study" to Doctor J. H. Williams, Cyanamid's Director of Chemical and Biological Research, Lederle Laboratories Division:

> In Mr. Martin's memorandum of January 22 to Doctor Phelps on this subject, he showed there were four (4) samples which contained 1 to 6% tetracycline. At that time Mr. Martin did not have the dates of preparation of these samples. Mr. Wilhelm has gone back into his research books and reports that these were prepared during the month of March in 1948. (CX 111 B.)

It appears from the face of this memorandum that copies thereof were sent to various Cyanamid officials, including Edelblute. Also written on the memorandum were the words, "All copies were ret'd & destroyed." In March 1954, Cyanamid developed a method for determining the tetracycline content of Aureomycin and recommended that the method be used "as a routine assay." Cyanamid did not disclose this information or other data which is obtained on inherent production to the Patent Office.

Various documents later prepared by Edelblute show that he knew precisely the type of information the patent examiner desired but that he disagreed with the examiner as a matter of law that the presence of tetracycline in Aureomycin or Aureomycin fermentations was a proper basis for rejecting tetracycline product claims.

14. At the aforesaid meetings in November, Malcolm and McKeen entered into the following agreements which were to become effective after the proposed interference had been declared:

1. Cyanamid was to license Pfizer to make Aureomycin (for chemical conversion into tetracycline) at a royalty rate of 2½% based on tetracycline sales.

2. Cyanamid was to give Pfizer technical know-how on the production of Aureomycin and to open its plants to visits by Pfizer technicians and executives.

3. The parties agreed to exchange priority information and to determine which company would concede to the other the invention of tetracycline.

4. The parties agreed to license each other under any tetracycline product or process patent that might issue to either.

The interference was declared on December 28, 1953, and the aforementioned agreements were executed on January 11, 1954.

Malcolm and McKeen also entered into an unwritten agreement that Cyanamid would furnish bulk tetracycline to Pfizer to enable Pfizer to begin selling this product as soon as possible. Cyanamid had already begun selling tetracycline on November 16, 1953, and the pur-

pose of this agreement was to permit Pfizer to cut down Cyanamid's "lead time" on the sale of tetracycline. Shipments of tetracycline from Cyanamid to Pfizer began prior to the execution of the aforementioned written agreements.

Subsequent to the execution of the aforementioned written agreements, Pfizer and Cyanamid exchanged information for the purpose of ascertaining which had priority on the discovery of tetracycline. After review of each other's proof, Cyanamid conceded priority to Pfizer and on or about February 2, 1954, Cyanamid filed a concession of priority with the Patent Office which awarded priority to Pfizer's Conover application on February 9, 1954.

By letter dated February 4, 1954, a Cyanamid patent official advised Malcolm that "Steps are being taken to try to effect early issue of the United States patent to Pfizer." (CX 1034.) On January 29, 1954, certain Pfizer officials, including McKeen, informed a group of security analysts that in the event Pfizer obtained a patent on tetracycline it would take a determined stand against others entering into the field and that the company did not anticipate licensing others to manufacture tetracycline. These officials also stated on the same occasion that both Pfizer and Cyanamid expected to take this stand so that overproduction might be avoided.

15. The interference between Cyanamid and Pfizer's applications was terminated on February 9, 1954, as a result of the concession of priority by Cyanamid. Within a few days Pfizer's patent counsel were advised that the Patent Office intended to declare a second interference. In this connection, Bristol had filed continuation applications in the Heinemann matter in January 1954, claiming tetracycline hydrochloride, and had persuaded the patent examiner that tetracycline hydrochloride was patentably distinguishable from tetracycline. The purpose of the second interference was to determine who had priority on the discovery of tetracycline hydrochloride.

After receiving word of the proposed interference, Pfizer's outside patent attorney, Hutz, promptly relayed this information to Cyanamid's house patent counsel, Edelblute. Murphy, a Pfizer official, was later advised by Edelblute that Cyanamid would not be made a party to this interference. A memorandum by Murphy of the telephone conversation between these two officials reads in part as follows:

> Mr. Edelblute is going to Washington on Thursday to discuss the case with the Patent Examiner and to determine why Cyanamid has not been included in a new interference if, in fact, one is being set up. This course was previously discussed with Mr. Hutz and Mr. Edelblute, and it seems to be the best possible approach to the problem, since Cyanamid having received an Office Action has every reason to go to the Patent Office to discuss the matter.

However, it is questionable that any appeal to a higher authority such as the Supervisory Examiners or the Commissioner should be made by Cyanamid at this time if they are not admitted to an interference * * *.

Mr. Edelblute has promised to send us a copy of the Office Action received by Cyanamid in this case and will inform us by phone of the outcome of his interview with the Examiner. (CX 916.)

16. The second interference was declared on March 2, 1954, after Edelblute had persuaded the patent examiner to include Cyanamid in the proceeding. The parties to the interference were Pfizer (Conover application), Bristol (Heinemann application), and Cyanamid (Minieri application). Although Cyanamid had conceded priority on tetracycline to Pfizer, it took the position before the patent examiner that tetracycline hydrochloride was not patentably distinct from tetracycline. This argument, if accepted, would have resulted in a dissolution of the interference since this proceeding had been initiated on the assumption that the two products were patentably distinct. Thus, Cyanamid joined with Pfizer in opposing Bristol's attempt to delay the proceeding although such opposition to Bristol's motions for extension of time was contrary to Cyanamid's own financial interest. Bristol had begun to sell tetracycline during the interference and was attempting to delay any possible issuance of a patent on this product. If a tetracycline patent would issue to Pfizer, Cyanamid would be required to pay royalties of about $50,000 a month on its sale of this product under the aforementioned licensing agreement with Pfizer. Being aware of this fact, Bristol's counsel stated that it was strange that Cyanamid wanted to see the interference terminated because it would then have to pay royalties. In response, Edelblute informed the patent examiner that "Cyanamid would rather pay royalties to a bona fide patentee than see the pharmaceutical business in which it has a major interest ruined by irresponsible price cutting." (CX 12, p. 115.) Bristol had not been cutting prices but Edelblute's testimony shows that he believed that the entry of other sellers in the market would lead to price-cutting.

17. In early September 1954, during the course of the second interference, Pfizer informed Schwartz that some means had to be found to stop Bristol from making and selling tetracycline. Pfizer, however, had no lawful means of doing so. On September 29, 1954, Cyanamid sued Bristol, alleging infringement by Bristol of the Duggar patent. This was about five months after the alleged infringement began but only three weeks after Pfizer's decision that Bristol must be stopped. Thereafter, on October 14, 1954, the interference was dissolved and the patent examiner ruled that tetracycline hydrochloride was not patentably distinct from tetracycline and he further

ruled, on his own motion, that the product tetracycline and its hydrochloride were not patentable. As a result of this action, Cyanamid believed that no patent would ever issue on tetracycline and, within two months, settled its suit against Bristol and granted Bristol a license under its Aureomycin patents to make up to 6 percent Aureomycin in the production of tetracycline.

The aforementioned ruling relating to the patentability of tetracyline and its hydrochloride was based on the patent examiner's assumption that tetracycline was inherently produced by the processes disclosed in the Duggar and Niedercorn (Aureomycin) patents, and was, therefore, unpatentable. The Minieri application filed by Heyden on September 25, 1953, had disclosed that the microorganism used to prepare tetracycline belonged to the species used in producing Aureomycin and that Aureomycin was coproduced in the Minieri fermentation process. On the basis of this information, the patent examiner speculated that tetracycline was coproduced with Aureomycin in the processes disclosed in the Duggar and Niedercorn patents.

18. As hereinbefore stated, the second interference before the Patent Office was dissolved on October 14, 1954,, because it appeared to the patent examiner that tetracycline had been produced in the Duggar and Niedercorn processes and was, therefore, unpatentable. The patent examiner stated in this connection:

The interference count is unpatentable over the disclosures of Duggar U.S. 2,482,055, Sep't 13, 1949 and Niedercorn U.S. 2,609,329, Sep't 2, 1952, and the interference is dissolved. Duggar and Niedercorn each produce an antibiotic, disclosed as "Aureomycin" by a fermentation process employing *Streptomyces aureofaciens* and mutants thereof. The antibiotic is identified as an antibiotic by assay against bacteria. It appears from the disclosure of Minieri et al (a party to this interference in an application available to all the parties) that tetracycline is *also* produced in such a fermentation process and that larger proportions thereof are produced when the amount of chloride in the fermentation medium is low * * *. Minieri et al clearly and specifically disclose that the microorganism used to prepare *tetracycline* belongs to the Duggar et al U.S. 2,482,055 species and that "the characteristics are identical with those exhibited by a known culture of *S. aureofaciens*". While neither Duggar or Niedercorn may have realized that tetracycline was in fact produced, they did appreciate, and disclose, that the product was an antibiotic. No invention is involved in the *identification* of the tetracycline and its hydrochloride inherently produced by the reference processes (see In re Lieser 1947 C.D. 447; and Allen et al v. Coe 1943 C.D. 55). It has long been held that a purer form of an old product is not inventive and the (apparent) mixture of the prior art meets the count (see Parke-Davis v. Mulford 189 F 95 and In re Kebrich 96 US PQ 411). (Emphasis in original.) (CX 12, pp. 443–44.)

Thereafter, the patent examiner rejected the product claims in each of the pending applications because of inherent production and repeated almost verbatim the above-quoted language.*

This language of the patent examiner was interpreted by interested parties at the time to mean that the examiner considered the mere presence of tetracycline in Aureomycin fermentations as sufficient ground for holding tetracycline to be unpatentable. On October 27, 1954, Edelblute wrote:

* * * To my way of thinking, there are two points of error in the Examiner's decision concerning his holding of unpatentability of tetracycline over Duggar and Niedercorn. In the first place, he assumed that tetracycline was inherently produced by the disclosure of these patentees * * *.

* * * Secondly, *the Examiner is in error as a matter of law.* There are many decisions, some recent, which hold that *the mere presence of a substance as an impurity in an old material does not negative patentability to that substance when its presence was unsuspected, unknown, and not utilized* * * *. (Emphasis added.) (RACX 878.)

Gilmore, chairman of the board of Upjohn, made the following notes on October 14, 1954, at a conference with his top executives:

Tetra 1%—99% Aureo
"99%—1%"

* * * * * * *

When made Aureo also made tetra so old and not patentable. (CX 156.)

The following statement was made by Bristol on November 1, 1954:

This dismissal as to all the parties was an action taken by the Examiner on his own motion and was on the ground that some tetracycline was inherently produced in the processes for producing Aureomycin * * * long prior to the filing of any of the applications and that, consequently, it was not now patentable to any of the parties. (RBX 903 D-E.)

Cyanamid officials, other than Edelblute, knowing the basis of the patent examiner's rejection of tetracycline product claims, were convinced that "no valid patent on the product tetracycline would be issued to any applicant by the Patent Office."

A Patent Office official, Manuel C. Rosa, the direct superior of the aforesaid patent examiner, testified as follows with respect to the above-mentioned rejection of the tetracycline product claims:

Well, as I said before, the examiner in saying "No invention is involved in the identification of the tetracycline and its hydrochloride," is a statement of a principle which I tried to state * * * and that was that it is usually sufficient for the purpose of rejecting broad product claims to show that a material in question was an ingredient in a mixture which existed in the

* Attached to these Findings and a part thereof is a chart showing the history of the various applications [pp. 1800–1803 herein].

1747 Findings

prior art, let me put it that way, instead of known to the prior art — existed in the prior art.

Now, that's a general principle.

The examiner here, as has already been brought out, doesn't say that Duggar and Niedercorn admit that there was any present, but he says that in view of what he has learned from the Minieri application, that the Duggar and Niedercorn apparently contain it.

Now, that's his position at this stage and that's the position he took when he dissolved the interference. No review was sought at that time. No one objected to the dissolution of the interference. The examiner carries it over into this particular — into each of the applications previously involved in the interference. (Tr. 2521.)

19. Pfizer scientists during 1953 and 1954 worked on the development of methods to produce tetracycline by direct fermentation. Sometime prior to October 9, 1953, a Pfizer scientist subjected a 250 mg. capsule of commercial Aureomycin to a Craig countercurrent separation procedure and found tetracycline or at least indications of tetracycline. (CX 37, p. 88; Tr. 2835–2837.) Pfizer scientists discovered that some strains of *S. aureofaciens* produced tetracycline. On November 12, 1953, Dr. Fred Tanner and other Pfizer scientists filed in the Patent Office a patent application for a process of making tetracycline by direct fermentation. The microorganism disclosed in the application was alleged to be of a species other than *S. aureofaciens*.

On October 15, 1954, one day after the dissolution of the second interference, Dr. Murphy, a former Pfizer research chemist and then employed by Pfizer as a patent agent, issued memoranda to two Pfizer scientists, Dr. Fred Tanner and Dr. Virgil Bogert, instructing them to conduct work on the question of coproduction of tetracycline with NRRL–2209, the strain of *S. aureofaciens* which had been deposited by Cyanamid in the public culture collection of the Northern Regional Research Laboratory maintained by the Federal Government. It was made clear to these scientists that the work was in connection with the prosecution of the Conover application and that the results might be used in preparing affidavits for the Patent Office. Tanner was instructed to summarize all fermentation work that had been conducted to date with NRRL–2209, "particularly with respect to the proportion of Aureomycin and tetracycline produced in media specifically described or generally disclosed in the Duggar and Niedercorn Aureomycin patents." He was also instructed to conduct fermentations with NRRL–2209 in accordance with the examples set forth in the Duggar and Niedercorn patents and to have each fermentation broth checked for total broad spectrum antibiotic potency. Bogert, in turn, was instructed to recover and purify by the Pidacks

Florisil-column method (a method of recovery referred to in the Duggar patent) the antibiotics present in the fermentation broths prepared by Tanner and to determine the total broad spectrum potency. He was also told to determine the Aureomycin and tetracycline content of the recovered products. In connection with the latter instruction, Murphy stated, "This presumably will be determined primarily by paper chromatography tests. However, if other methods are available for determination of this ratio, these should also be utilized." (CX's 55, 57, 66.)

The Pidacks Florisil-column procedure, a column chromatography procedure disclosed in the Duggar patent as a method of recovering Aureomycin from a fermentation broth, involves a process by which the filtered fermentation liquor is passed through a column filled with a substance to which the antibiotics adhere as the broth passes over it. The column is then "eluted" (washed out) with a proper solvent. As the solvent, containing both antibiotics and impurities, comes out of the column, it is segregated in portions called "bands" or "fractions". Dr. Bogert, in a test run on a Niedercorn broth in November 1954, determined that most of the tetracycline present is destroyed when one strictly follows the Pidacks procedure, but that the result could be obviated by a slight modification of the procedure. (CX's 59, 60; Tr. 4413; CX 58-C.)

Paper chromatography is a method that can be used for identifying tetracycline and many other substances. It consists of placing a spot of the material being examined on a strip or sheet of filter paper and allowing a solvent to flow over the paper by capillary action; The paper is removed from the solvent, immobilizing spots of the material which have migrated. Previous tests have established that tetracycline and other products have certain characteristics in the rate at which they migrate. The results of the paper chromatography can be compared against these standards. In the case of an antibiotic such as tetracycline, the spots can be identified by placing the sheet or strip on a seeded agar plate which will reveal the presence of antibiotic substances. Paper chromatography can be used to determine the percentages of tetracycline present by measuring the zone of inhibition of the bacteria test organism present in the agar medium.

The Craig countercurrent separation procedure is a method which can be used to separate tetracycline from Aureomycin. It is based on the manner in which a substance will distribute itself between two immiscible solvents. Two substances which have different distribution coefficients, such as tetracycline and Aureomycin, can be separated by this method.

20. On October 19, 1954, Werner H. Hutz, Pfizer's outside patent counsel handling the Conover application, wrote a letter to Murphy expressing great interest in the results of the experiments. (CX 1027.) Notwithstanding this expressed interest, he testified during the hearing that, within two days of this date, he had ordered the work stopped because it occurred to him that he did not know the information the patent examiner would require to overcome the rejection of Pfizer's patent claims. (Tr. 3913.) According to Bogert, Dr. Murphy requested him "not to do any more work or make any more entries" in his official notebook. (CX 37, p. 20.) The record shows that Bogert continued the tests but recorded the results outside his regular records. (CX 58.)

Pursuant to the original instructions given by Murphy, Dr. Tanner prepared several broths, among which were two broths prepared in accordance with the specifications set forth in Niedercorn Example I. One of these broths had a bio-assay potency of 75 micrograms per milliliter (calculated as Aureomycin). Bogert applied a modified Pidacks procedure to this broth and obtained a number of fractions which were found by paper chromatography to contain tetracycline. These findings were recorded as:

Fraction	Paper (percent)	Chromatography
4	<5	Tetracycline.
5	5	Do.
6	5	Do.
7	5	Do.
8	10	Do.
9	8	Do.

(CX 58C.)

Bogert testified that these tests showed tetracycline to be present and to be present in quantities "not more than five per cent." (Tr. 4412.) Bogert did not attempt to isolate the tetracycline. The Commission has found on the basis of expert testimony that tetracycline could have been recovered from these fractions as of October 1954 by the Craig countercurrent separation procedure. (Tr. 2826, 11,032, 11,043–45.)

21. On November 29, 1954, Hutz and Murphy conferred with the patent examiner. In accordance with Patent Office practice, a summary of what transpired at this conference was drafted and filed by Hutz at the next conference on December 8, 1954:

At the outset of the interview, the Assistant Examiner agreed that the discovery of the new antibiotic, tetracycline (and its salts), constituted a major advance in the art, that should merit patent protection. He further conceded that neither the Duggar nor the Niedercorn patents contains any disclosure

whatsoever of this important new antibiotic nor the slightest hint as to the possible existence thereof. However, he stated that applicant's product claims appeared to be anticipated by the possible, although wholly unappreciated, co-production of appreciable amounts of tetracycline in the fermentation processes described in the cited patents.

It was pointed out to the Assistant Examiner that there is no reasonable basis for his speculation as to the co-production of tetracycline in the prior art processes, and that the same rejection had previously been made and withdrawn in the prosecution of the Heinemann, et al. application * * *. The Examiner, however, felt that he was justified in relying upon the disclosure of the Minieri et al. application Serial No. 382,637 as giving rise to a rebuttable assumption of inherent production.

Applicant's counsel denied that any such prima facie assumption is justified. He pointed out that there are no statements whatever in the Minieri et al. application to the effect that most strains of *Streptomyces aureofaciens* are capable of producing tetracycline under previously known fermentation conditions. Minieri et al. refers specifically only to the use of a new strain (Texas organism) and a mutant thereof (Strain UV-8) that are obviously not the same as the known strain deposited by Duggar and identified as NRRL-2209. On page 14, second paragraph of their disclosure, when speaking of the possible use of other strains, Minieri et al. state that such are limited to those which produce tetracycline "in concentrations making possible the recovery of the therapeutic product". This is certainly no indication that the NRRL-2209 strain possesses such ability, particularly under the conditions described in the Duggar and Niedercorn patents.

The available evidence is overwhelmingly contrary to the Examiner's assumption. Minieri et al. themselves, in their brief on their motion to add fermentation counts in the interference * * * have stated that tetracycline could previously be produced only by deschlorination, and that there is no evidence of inherent production by the prior art processes. Most striking of all is the fact that the assignee of the Duggar and Niedercorn et al. patents, who manufactured literally tons of chlortetracycline (Aureomycin) according to the methods described therein, failed to discover any tetracycline in such large-scale manufacture, although it devoted extensive research to the recovery, purification and properties of its patented antibiotic. Said assignee first claimed tetracycline (and its salts) made by a *deschlorination* process in its Boothe et al. application Serial No. 342,556 filed March 16, 1953, some five years after the Duggar and Niedercorn patents were filed. This should conclusively refute the tenuous basis for the Examiner's unwarranted assumption.

It was further submitted to the Examiner that there is no proper basis in law for his rejection, even assuming that his speculation as to inherent co-production were correct. There are numerous court decisions establishing the rule that "novelty is not negatived by any prior accidental occurrence or production, the character and function of which was not recognized until later than the date of the patented invention sought to be anticipated thereby" (1 Walker, 6th Ed., Sec. 106). It follows that a wholly unrecognized occurrence of some ineffective amount of tetracycline in a prior art product could not anticipate applicant's claims. The disclosure or use of such a product as an antibiotic makes no difference, since it would display none of the distinctive properties that make tetracycline such an important advance in the art.

1747 Findings

Despite the foregoing arguments, the Examiner adhered to his position that he would not withdraw his rejection of the product claims, unless applicant submits a showing overcoming his speculated basis for such rejection. He explained that he would require evidence that fermentation broths produced strictly in accordance with the Duggar and Niedercorn disclosures, using the deposited strain NRRL–2209, do not contain recoverable amounts of tetracycline. He stated that the absence of such amounts of tetracycline would have to be established by failure to recover this antibiotic in a clearly identifiable form according to present day efficient methods for the separation thereof from fermentation broths.

While applicant's counsel did not concede that there is any necessity for such a showing, he ventured the opinion that it could be made and stated that he would explore the matter in view of the great urgency of this case. The Examiner made it clear that he would not insist on a categorical averment that the fermentation broths prepared according to the cited patents contain no tetracycline whatsoever. He evidently appreciates the impossibility of proving its nonexistence and is not concerned about useless trace amounts which cannot be separated from the broths by methods now recommended for recovery of the new antibiotic.

This summary shows that Hutz and Murphy argued to the examiner that there was no reasonable basis for his speculation as to coproduction of tetracycline in the prior art processes and that "The available evidence is overwhelmingly contrary to the Examiner's assumption." The patent examiner informed Pfizer's representatives that he would withdraw his reject of Pfizer's tetracycline product claims if Pfizer could demonstrate that tetracycline could not be recovered in clearly identifiable form from fermentation broths produced strictly in accordance with the Duggar and Niedercorn disclosures, using the strain *S. aureofaciens* NNRL–2209 which had been deposited by Cyanamid with the Northern Regional Research Laboratory as part of its disclosure requirements in receiving the Duggar patent.

The summary clearly indicates that the examiner was interested in knowing whether any perceptible or identifiable amount of tetracycline could be recovered, extracted, or isolated from the broths, or from any amorphous product recovered from the broths, using the best methods available for this purpose. The record shows that the examiner based his rejection on the speculation that tetracycline was present in a mixture known in the prior art. The examiner did not regard "useless traces" of tetracycline as establishing that Conover's claims were anticipated, but regarded only "clearly identifiable" tetracycline as anticipation.

During this conference, it was decided that at least three recovery procedures, each selected from three pending patent applications (Pfizer's Bogert-Walsh application, Cyanamid's Minieri application, and Bristol's Heinemann application), be used in the tests to be per-

formed by Pfizer scientists. The examiner, however, did not limit Pfizer to these three procedures if its scientists had knowledge of other suitable isolation methods. On December 8, when the results were submitted, Hutz represented these procedures as being the best designed for isolating tetracycline.

As found above, the examiner was speculating that tetracycline may have been produced along with Aureomycin in one or more of the Duggar and Niedercorn processes. The Niedercorn patent contained a large number of examples of media, however, and Pfizer used Example 28. Hutz testified that the examiner selected this example himself and required Pfizer to use it because it appeared to contain only a trace of chloride ion. It is evident, however, that the examiner was interested in the possible production of tetracycline in any of the Niedercorn examples. The Pfizer representatives did not disclose that Bogert had previously found that NRRL–2209 fermented in the medium described in Example I of Niedercorn produced a broth of 70 micrograms per milliliter, and that using a modified Pidacks method and paper chromatography he had found approximately 5 percent of the filtered broth to consist of tetracycline.

Furthermore, Tanner, in September of 1954 as part of a general research project to determine the production of tetracycline by various means of fermentation, had fermented NRRL–2209 in a Niedercorn 28 medium and had found the resulting broths to be less than 10 micrograms per milliliter. These broths were so poor in antibiotic potency that they were classified as containing no Aureomycin or tetracycline. These findings, which were relevant to the patent examiner's determination of which examples in Niedercorn to use, were not disclosd to him. When Tanner prepared the affidavit-test broths, the Niedercorn Example 28 had approximately the same low level of potency as the similar broths prepared by Tanner in September.

22. After the oral interview of November 29, Murphy immediately notified Tanner and Bogert that tests were to be conducted for the Patent Office to determine whether tetracycline could be recovered from Duggar and Niedercorn Example 28 broths using the three recovery procedures described in the Bogert-Walsh, Minieri, and Heinemann applications. Tanner prepared two broths—one as representative of the example set forth in the Duggar specifications and one as representative of the Niedercorn Example 28 broth. These broths were respectively designated as broths 1771A and 1771B. When these broths were turned over to Bogert, both biological and

chemical assays were made of these broths by other Pfizer technicians at the request of Bogert. The potency of 1771A was assayed at 6.9 micrograms per milliliter (calculated as Aureomycin) by biological assay (8.3 by chemical assay). The potency of 1771B was assayed at 5.2 micrograms per milliliter (as Aureomycin) (14.3 by chemical assay). The record establishes that for low potency broths, the biological assays are more accurate. These potency figures were unusually low in comparison to the potencies set forth in the Niedercorn patent.[1] Although Niedercorn did not specify the microorganism used, Example 28 discloses that a broth potency of 274 micrograms of Aureomycin per milliliter was obtained. Other examples set forth in Niedercorn show potencies ranging from approximately 100 to 400 micrograms per milliliter.

Notwithstanding the low potencies of the test broths, the papers filed by Pfizer with the examiner indicated that these broths were "representative" of the Duggar and Niedercorn broths. The potency figures were not set forth or otherwise indicated. Expert testimony establishes that there is no way to calculate the potencies of the test broths from the data contained in the affidavits. (Tr. 1912, 2869.) The record also clearly establishes that the low potencies of the broths were a crucial factor in Pfizer's failure to recover tetracycline. (Tr. 1933–34, 4439.) Under these circumstances, the statement that the broths were "representative" of the Duggar and Niedercorn broths was clearly misleading.

23. In this connection, the affidavit prepared by Tanner omitted a fact which may have been material to the patent examiner's determination of whether Niedercorn Example 28 was sufficiently duplicated. In his affidavit, Tanner indicated that the entire forty-hour fermentation (tank fermentation) was conducted in a medium having a pH value of 6.7. The Niedercorn patent states that for maximum growth it is necessary that the pH of the fermentation medium be controlled within rather narrow limits and that "Highly effective growths may be obtained within the range of about 5.0 to 8.0. Best results are obtained within the range of approximately 6.4 to 7."

In fact, Tanner's laboratory notes show that the medium was initially adjusted to 6.8 (which was recorded in the affidavit as 6.7), but after sterilizing the medium preparatory to inoculation, he found the pH to be 8.1. (CX 61.) Without further adjustment of the pH, Tanner inoculated the medium and began the fermentation with the

[1] The example disclosed in the Duggar patent describes the potency obtained by Duggar as 1,000 to 1,500 arbitrary units/ml. There is no clue in the Duggar patent as to what this means in terms of micrograms of Aureomycin per milliliter.

pH at 8.1. Six and one-half hours later Tanner returned to the laboratory and found the pH still tested at 8.1. Tanner then adjusted the medium with sulphuric acid to bring down the pH value. During this six and one-half hour period, it was observed that no growth of the organism occurred. These facts were not disclosed to the patent examiner. Instead, the affidavit clearly conveys the false impression that the pH was constantly kept within the optimum range.

24. The two test broths prepared by Tanner were turned over to Bogert for recovery work. As noted before, Bogert had these broths assayed by both biological assay and chemical assay methods. Although the assays showed the broths to have little antibiotic content, Bogert proceded to apply three commercial recovery procedures which were designed for direct recovery of tetracycline from higher potency broths. For example, one procedure was to be applied to a broth containing at least 100 micrograms per milliliter of tetracycline. The test broths used by Bogert, however, had only 5 to 7 micrograms of tetracycline and Aureomycin combined. Nevertheless, Murphy and Hutz represented that the techniques used were the best procedures designed for recovering any tetracycline present in the test broths.

In fact, other procedures were available which were more suitable for recovering tetracycline from low potency broths where the percentage of tetracycline approximates 5 to 10 per cent of the antibiotic material. These procedures were the column chromatography method and the Craig countercurrent separation method. The latter method could have been used in conjunction with column chromatography or with the Bogert-Walsh recovery method. (Tr. 11,031–3, 11,042, 11,052.)

The record shows that Murphy and Hutz knew that the examiner was under the impression that the Pidacks Florisil-column chromatography method was suitable only for obtaining Aureomycin fractions (and not tetracycline) from fermentation broths. Before representing to the examiner that the procedures used were the best available, they were under a duty to ascertain from Pfizer scientists what procedures were available. The record shows that earlier in November Bogert had successfully applied a modified Pidacks method to broths containing tetracycline. The record shows that Murphy, however, instructed Bogert to use only the three procedures described in the Bogert-Walsh, Minieri, and Heinemann applications. (Tr. 4273.)

25. The papers filed by Hutz with the Tanner-Bogert affidavits stated the following:

The affidavit of Virgil V. Bogert describes his unsuccessful efforts to recover products clearly identifiable as tetracycline from the fermentation broths pre-

pared by Fred W. Tanner, Jr., using several recovery procedures recently recommended for this purpose. The procedures were selected, because they correspond to preferred procedures described in pending patent applications dealing with the separation of tetracycline from fermentation broths. There are, of course, endless further recovery procedures that might be attempted, most of which would be entirely unsuitable for any practical utilization, but it is understood that the Examiner does not expect an elaborate research program to be carried out in an effort to pick up useless traces of tetracycline that might possibly be present in the broths. The procedures that have been tried are best designed to show whether appreciable amounts of tetracycline are produced, when following the fermentation procedures described in the references. (CX 4, pp. 38–39.)

Bogert's affidavit describes in detail the recovery techniques he applied. A few amorphous products were recovered, all having a low antibiotic content. As to the amorphous product obtained by the procedure taken from the Bogert-Walsh patent application, Bogert stated:

This product was tested in a manner that he knows is capable of detecting even a small proportion of tetracycline in the presence of chlortetracycline and showed only chlortetracycline. (CX 4, p. 43.)

The tanner-Bogert affidavits were submitted by Hutz and Murphy to the examiner on December 8, 1954, together with their own "Remarks" [2] summarizing their version of the November 29 conference and an amendment of seven new claims. After examining these papers, the examiner requested more information as to the possibility of recovering tetracycline. The next day, December 9, Hutz and Murphy conferred again with the examiner. They submitted a supplemental affidavit signed by Bogert and filed the following remarks:

As regards the affidavit of Dr. Bogert, the Examiner indicated that the details of the test referred to at the middle of page 3 should be supplied. He further required that some explanation be furnished why no further efforts were made to separate and recover clearly identifiable tetracycline from the various amorphous materials showing some degree of biological potency, that were recovered in the various procedures described. It was immediately pointed out to him that the amounts of materials were so small and their potencies so low in each case, that it would be futile to attempt to recover identifiable tetracycline therefrom by known procedures. He requested that such explanation be set forth in affidavit form, and it was agreed that a supplemental affidavit by Dr. Bogert to this effect would be made of record.

Such supplemental affidavit is submitted herewith. It explains why no further efforts were made to work up the small amounts of amorphous materials recovered, instead of the crystalline tetracycline or at least high potency crude tetracycline that should have been obtained had the broths contained appreciable amounts of this antibiotic. (CX 4, pp. 55–56.)

[2] See paragraph 21 *supra*.

Bogert's supplemental affidavit recited that he had applied an acid color test which should show whether the amorphous product recovered from broth 1771A by Procedure A contained 20 percent or more tetracycline. He concluded:

> Based on these results and on his experience with the results of a great many such tests on materials containing tetracycline, chlortetracycline and mixtures thereof, he is convinced that not nearly as much as 20% of the potency of the amorphous material could be due to the presence of tetracycline, in fact there was no indication whatever of the presence of tetracycline. Assuming that the maximum possible proportion of the total potency due to tetracycline is 10%, this means that the 0.36 grams of amorphous material cannot contain more than about 0.009 grams of tetracycline. He does not know of any method whereby any part of such a minute amount of tetracycline could be separated and recovered in clearly identifiable form from the amorphous material. (CX 4, p. 58.) [3]

Bogert's affidavit further stated that in each instance in which amorphous material had been recovered, the amount was so small and the potency so low that he knew of no method whereby "any part of the minute amount of tetracycline conceivably present could be separated and recovered in a clearly identifiable form." On the assurances given in the aforementioned affidavits and remarks, the patent examiner on December 9, 1954, granted a notice of allowance to Pfizer and the tetracycline patent was issued to Pfizer on January 11, 1955.

26. As hereinbefore mentioned, Cyanamid had, in December 1954, settled its infringement suit against Bristol and had agreed to grant Bristol a license under its Aureomycin patent to manufacture and sell tetracycline. Bristol knew at this time that it could not obtain a patent on tetracycline but knew that there was at least some possibility that Pfizer might obtain one. It realized that the license from Cyanamid would be worthless if Pfizer obtained a patent on tetracycline and further knew that if Pfizer obtained such a patent it might try to prevent Bristol from manufacturing and selling tetracycline. On January 3, 1955, Bristol filed an affidavit, the Taylor affidavit, with the examiner stating in effect that numerous samples of Aureomycin products had been found to contain 2 to 4 percent tetracycline hydrocholoride and that samples of two Aureomycin products had been found to contain tetracycline in similar amounts. The affidavit further stated that pure tetracycline had been separated from a sample of commercial Aureomycin. This information, however, did not constitute

[3] Bogert later testified that the figure 10 percent was used because the acid color test should have indicated amounts down to about 10 percent even though the control test had 20 percent tetracycline present.

adequate proof of inherent production of tetracycline in the Duggar and Niedercorn processes as disclosed in the prior patents since the fact that tetracycline was contained in some commercial Aureomycin samples did not mean that its production was inherent or intrinsic in the processes in question using the NRRL–2209 microorganism. This was the microorganism that had been put on public deposit by Cyanamid as part of the disclosure requirements of its Aureomycin patents and was the microorganism that the patent examiner required Pfizer to use. Thus, the Taylor affidavit did not put the patent examiner on notice of inherent production in the prior art, even if it be assumed that the examiner saw the affidavit before the Conover patent issued.

The Commission therefore finds that the misrepresentations of fact made and the information withheld by Pfizer and Cyanamid before the patent examiner were material to the allowance of the Conover claims and the issuance of the Conover patent to Pfizer. The Commission further finds that Cyanamid accepted a license under said patent with knowledge that it had misrepresented material facts to the patent examiner relating to the patentability of tetracycline.

27. On the same day that Pfizer received a patent on tetracycline, January 11, 1955, it brought infringement suits against Bristol, Squibb, and Upjohn, seeking damages and a restraining order preventing them from marketing tetracycline. Squibb and Upjohn had been buying tetracycline from Bristol in bulk and selling it in dosage form to the drug trade for several months. Bristol entered into bulk purchase agreements with Squibb and Upjohn, respectively, on September 1 and 14, 1954, under the terms of which Squibb and Upjohn agreed to indemnify Bristol for any losses as a result of an infringement judgment under a tetracycline patent. Both Squibb and Upjohn knew at the time they entered into this agreement that tetracycline might not be patentable. Both had been so informed by Bristol, and Squibb had already made tests to determine whether tetracycline was, in fact, coproduced with Aureomycin. On September 20, 1954, Gilmore, chairman of the board of Upjohn, made the following comments in explanation of Upjohn's decision to buy bulk tetracycline from Bristol:

I think Mr. Harrop & Gordon Hueschen our own Patent man feel that Bristol's Patent chances are 40% against Pfizer's 60% — & that if Pfizer wins out the chances are about 50–50 in regard to suing us or settling for a licence.

There are some technical reasons which Mr. Harrop will explain that makes Bristol feel that if the Patent Case came to trial that all Patents might be thrown out. I believe Mr. Harrop feels there is only a 50–50 chance on this.

I refer to the fact that tetracycline was present as an old product along with Terramycin (sic) when it was patented but wasn't claimed then & can't be patented now.

Pfizer might settle rather than risk its position on Tetracycline — & throw the product open to all comers.

Bristol tells us that most everyone in the Industry has been after Bristol trying to get in on Tetracycline. (CX 942.)

Some months later, a Squibb patent official made the following comment with respect to Squibb's decision to buy tetracycline from Bristol:

Although I did not participate directly in this decision, I was involved in several ancillary discussions and conferences thereon, and was aware of at least one of the bases thereof. This basis was that any patent issued with product claims covering tetracycline would be invalid, by virtue of tetracycline having been formed along with aureomycin. In support of this, our Laboratories had established that fermentation with the deposited culture of *Streptomyces aureofaciens* by the method described in the aureomycin patent resulted in the production of tetracycline along with aureomycin. Also they had established that early commercial preparations of aureomycin, of which we had obtained samples, could be demonstrated to contain tetracycline; and by calculation from analytical data, it could be established that these preparations contained from about 5–10% tetracycline. It was my impression that some of these commercial samples went back to 1948, hence the tetracycline invention was in use more than one year prior to the effective date of the Pfizer patent (parent application filed October 23, 1952). (CX 1066 A.)

These statements, as well as other circumstances of record, clearly show that all three firms hoped to obtain a license under any tetracycline patent that might issue to Pfizer. Knowing that such a patent would be of doubtful validity, they had good reason to believe that Pfizer might grant licenses rather than have a court rule on the validity of its patent.

The dissolution of the second interference on the ground of inherent production tended to confirm the views of the aforesaid respondents that tetracycline was unpatentable. Consequently, when Pfizer brought suit against them for infringing its newly acquired tetracycline patent, these three firms believed there was a definite chance that Pfizer would settle the suit on favorable terms. Bristol, Squibb, and Upjohn brought actions in the Southern District of New York seeking declaratory judgments that they were not infringing any valid claim of Pfizer's patent. They also filed an answer to Pfizer's suit, alleging, *inter alia*, that the tetracycline patent was invalid and void because it had been allowed by the Patent Office under

a mistake of fact induced by Pfizer and that the claims of the patent were unenforceable because of Pfizer's "unclean hands" arising from its misrepresentations of fact to the Patent Office in its prosecution of the application on which the patent was obtained. Throughout most of 1955, Bristol, Squibb, and Upjohn took numerous depositions of Pfizer's officials and technical workers and subpoenaed documents from Pfizer and Cyanamid. The information obtained by the pretrial discovery proceedings supported the aforementioned allegations. On October 4 and 7, 1955, Gilmore of Upjohn and McKeen of Pfizer discussed a possible settlement of the infringement suit. McKeen suggested at this time that Pfizer might be willing to work out a separate settlement with Upjohn if Upjohn would purchase its bulk tetracycline from Pfizer. Gilmore refused to make this settlement. In November 1955, Schwartz of Bristol and McKeen discussed a possible settlement of the suit whereby Bristol would obtain a license under Pfizer's tetracycline patent. The parties could not come to terms on the amount of royalties Bristol would be required to pay and no agreement was reached. On December 14 and 15, 1955, representatives of all parties met and an agreement was entered into to settle the suit under the terms of which Pfizer agreed to license Bristol, Squibb, and Upjohn in return for a royalty on their sale of tetracycline. This was precisely the arrangement that Bristol, Squibb, and Upjohn desired and which for more than a year they had expected to obtain.

By the terms of the settlement agreement, Bristol was granted a nonexclusive, unlimited license to manufacture and sell tetracycline. Although Squibb and Upjohn did not need licenses from Pfizer to sell tetracycline purchased from Bristol, they nevertheless solicited and received from Pfizer licenses to sell to the drug trade. The licensees were required to pay Pfizer a royalty of 3½ percent of net tetracycline sales.

28. Respondents contend that the reason for Pfizer's capitulation was not fear of exposure of its representations to the Patent Office but concern over the possibility that the defendants would use in their defense evidence which had come into their possession immediately prior to the settlement. In this connection, a private investigator, John Broady, had been hired by Pfizer's general counsel to make certain investigations at the time of the proceeding before the Patent Office and during the infringement litigation. On December 8, 1955, Broady was convicted of tapping the telephone wires of Bristol and Squibb. Respondents state that Pfizer settled the infringement suit because it was afraid the defendants would use the wire-tapping

incident as an "unclean hands" defense and because of the adverse publicity which it would receive. The Commission finds, however, from the evidence of record, including McKeen's testimony (Tr. 5093–4), that although the Broady incident may have been a factor in Pfizer's decision to settle the suit, it was not the determining factor. The Commission concludes from a consideration of all the circumstances that Pfizer settled the suit because it knew or had reason to believe that Bristol, Squibb, and Upjohn would be able to prove that Pfizer had obtained the tetracycline patent by means of false and misleading representations to the Patent Office or that the patent would otherwise be declared invalid.

29. When Cyanamid introduced the first broad spectrum antibiotic (Aureomycin) in December 1948, the price to the retailer was $15 for a bottle of 16 250 mg. capsules, which was a discount of 40 percent off the suggested retail price. Two months later, Parke, Davis announced it would market its broad spectrum product (Chloromycetin) and Cyanamid reduced its price one-third to all customers. Parke, Davis set the same price for its product. Early in 1950, Cyanamid learned of the imminent introduction of Terramycin by Pfizer, and on February 1, 1950, it reduced its published price 20 percent, resulting in a price to retailers of $8 on the same size bottle. This was met by Parke, Davis, but Pfizer set its price at $8.40, hoping to create an image of superiority for its product. Pfizer found it was unsuccessful and met the prices of its two competitors who had previously reduced prices to $6. A year later, Pfizer reduced prices on Terramycin, and the price on the 250 mg. capsule bottle of 16 became $5.10 to the retailer. Cyanamid and Parke, Davis met this reduction three days later on October 1, 1951. This was the last of the price reductions, and when tetracycline was introduced more than two years later, it was priced at the same level. At all times relevant to this action the prices of the broad spectrum antibiotics have remained at the same level to the retail and wholesale buyers.* After the introduction of tetracycline in late 1953, it rapidly assumed the outstanding position in the field. In 1954, the total sales of tetracycline were not much less than the combined sales of all other broad spectrum antibiotics, and from 1955 through 1958, the period covered by the record, the sales of tetracycline substantially exceeded the combined sales of all other broad spectrum antibiotics.

30. At the time tetracycline was introduced, the market for antibiotics consisted of the "prescription market," which includes retail

* The one exception is Pfizer's price to wholesalers on Terramycin which was higher than its price on tetracycline to wholesalers.

pharmacies, which sell directly to the patient on a doctor's prescription; wholesalers; and the "hospital market." The hospital market consists of (1) the private hospitals which are referred to as NPA hospitals (non-profit associations); (2) tax supported hospitals, referred to as CCS hospitals (city, county, and state); and (3) Federal institutions, including the Veterans Administration (VA), the General Services Administration (GSA), and the Military Medical Supply Agency (MMSA).

In addition to the published "list price" which was the suggested price to the public, there were published price schedules to the retailer, the wholesaler, the NPA hospitals, the CCS institutions, and, in some instances, the Federal agencies. The published price to the NPA hospitals was the same as the price to the retailers, which was a 40 percent discount from the suggested retail price. The published price to CCS hospitals was 16-2/3 percent below the price to retailers. The published Federal price was 16-2/3 plus 5 percent off the price to retailers. As to wholesale discounts, Cyanamid regularly granted a 16-2/3 plus 5 percent discount off the price to retailers on Aureomycin. On Terramycin, Pfizer granted a 20 percent discount off the price to retailers which is a smaller discount than the 16-2/3 plus 5 percent. Bristol used a 20 percent discount to wholesalers on all products. Squibb granted wholesalers a 16 percent on all antibiotics. Upjohn did not sell to wholesalers but used *del credere* agents on the very small portion of its sales that were not made directly to the retailer.

During November 1953, Cyanamid introduced tetracycline under the trade name of Achromycin. Cyanamid adopted the then existing prices of Aureomycin which had remained unchanged since October 1, 1951. Cyanamid used the dosage forms and package sizes then in existence and added two dosage forms (intramuscular and oral suspension) and a new size bottle of syrup (2 oz.). Pfizer, after it came into the tetracycline market in January 1954, with Tetracyn, soon adopted a different wholesale schedule than it had been using with Terramycin and followed the wholesale discount used by Cyanamid. The published prices of Pfizer's tetracycline products were identical with Cyanamid's published prices and the actual prices to wholesalers and retailers have also been identical with Cyanamid's and have not changed during the period covered by the complaint.

Bristol, when it came into the tetracycline market in April 1954, using the trade name Polycycline, was aware of the identical Pfizer and Cyanamid prices and established its own at the same levels and used the same dosage forms and package sizes. At the time of the

introduction of Polycycline, Bristol had a regular existing wholesale discount on all products of 20 percent off the price to the retailer. Bristol changed its wholesale discount on Polycycline to the discount used by Cyanamid and Pfizer on tetracycline. Bristol has continued to maintain its published prices in accordance with Cyanamid's and Pfizer's prices and the actual prices to retailers and wholesalers have been identical to those prices and uniform during the period covered by the complaint.

Squibb entered the tetracycline trade in September 1954, under the trade name of Steclin. Squibb adopted the identical published prices, and, with one exception, the same dosage forms and package sizes as used by Cyanamid, Pfizer, and Bristol. Squibb has maintained these prices at the same level and the actual prices to retailers have been the published prices. Squibb's wholesale prices differed from the other respondents' wholesale prices because Squibb used a 16 percent discount.

Upjohn entered the tetracycline market with Panmycin in October 1954, with the same published prices, dosage forms, and package sizes as those established by the other respondents . Upjohn's actual prices to retailers have followed the published prices and these prices have remained the same and identical with the other respondents' prices during the period covered by the complaint. The only exception in the price to retailers existed in the sales by *del credere* agents at a price higher than the industry price. These sales constituted only 7.78 percent of Upjohn's sales during the period covered by the complaint. Upjohn made no sales to wholesalers.

Some of the respondents had special promotional plans which they had in general use at the time tetracycline was introduced, but which they did not use for broad spectrum antibiotic products. Cyanamid had used a Lederle Purchase Plan whereby retail and NPA hospital customers could earn up to a 15% discount depending on the dollar volume purchased on a single order. Aureomycin and Achromycin were not items on which discounts were given, although they could be used in calculating the volume of a single order for the purpose of determining the discount that could be applied on the other products in the order. Bristol had volume discounts on products other than tetracycline. Squibb had an incentive earning plan in effect whereby retailers earned a 5% discount on many Squibb products, but Squibb's tetracycline products were not included in this plan. All the respondents' prices were based on single units with no discounts for large orders. By making special exceptions for tetracycline, the respondents removed any problems in their policy of maintaining identical prices.

31. The published prices to retailers by respondents during the period October 1951, until at least July 1958, the date of the complaint, are revealed by the following tabulation:

Tabulation of price to retailer of Tetracycline, Aureomycin and Terramycin

	Cyanamid Achromycin	Pfizer Tetracyn	Bristol Polycycline	Squibb Steclin	Upjohn Panmycin	Cyanamid Aureomycin	Pfizer Terramycin
Capsules:							
100 MG 25's	$3.61	$3.61	$3.61	$3.61	$3.61	$3.61	$3.60
100 MG 100's	13.77	13.77	13.77	13.77	13.77	13.77	13.77
250 MG 16's	5.10	5.10	5.10	5.10	5.10	5.10	5.10
250 MG 100's	30.60	30.60	30.60	30.60	30.60	30.60	30.60
Intramuscular: 100 MG vial	.94	.94	.94	.94	.94	----------	.94
Intravenous:							
250 MG vial	1.62	1.62	1.62	1.62	1.62	1.62	1.62
500 MG vial	2.91	2.91	2.91	2.91	2.91	2.91	2.90
Ped. Drops: 100 MG/cc 10cc	1.47	1.47	1.47	1.47	1.47	1.47	1.47
Oral Susp.: 250 MG/5cc 1 oz	2.54	2.55	2.54	2.54	2.55	----------	2.55
Syrup:							
125 MG/5cc 2 oz	2.54	2.55	2.54	2.54	2.55	----------	2.55
125 MG/5cc 16 oz	18.36	18.36	18.36	----------	18.36	18.36	18.36

Actual invoice tabulations from retail and wholesale sales by respondents in eight major cities are in the record (Commission exhibits 182, 184, 186, 188, 190). The eleven largest selling dosage forms (listed in the summary tabulation above) which constitute nearly all of respondents' sales were used. The tabulations cover approximately 15,700 transactions with retailers for the months of January 1955, January 1956, and January 1957. All sales, with the exception of ten transactions, were at the regular retail published prices as shown above. Approximately 3,000 transactions with wholesalers were tabulated during the same months and in the same cities. All sales were at the regular wholesale published prices with the exception of seven sales. Respondents do not dispute the accuracy of these tabulations.

The significance of identical and unchanging prices in the *prescription* market becomes apparent upon an examination of the proportion of sales made in this market to the total sales of tetracycline. The combined percentages of the total market during 1954 through 1957 represented by sales to retailers and wholesalers by all respondents according to the best figures available were:

	Percent
1954 (does not include sales of Upjohn)	80.35
1955 (does not include sales of Upjohn)	75.99
1956	73.67
1957	75.99

There were list price differences amounting to one cent on two dosage forms, the oral suspension and the 2 oz. bottle of syrup. These forms were of secondary importance in comparison to capsule and tablet dosage forms which outsold all others by a wide margin. Furthermore, the Commission finds that in the prescription market a difference in price of one cent is insignificant and for all intents and purposes the prices on these two dosage forms were identical.

32. Where tetracycline has been combined with other products such as antihistamines, sulfonamids, vitamins, and other antibiotics, the respondents have priced them at such a level above basic tetracycline as to be noncompetitive in price with the latter. The prices on these combined products have been identical and uniform as is shown by the following tabulation covering the price to retailers of similar brand products from the date of introduction of each product until at least the time of the complaint.

Respondents' Price to Retailer of Combination Products

Company	Product	Dosage form	Package size	Retail price
		Tetracycline-Vitamins		
Cyanamid	Aureomycin SF	250 mg cap	16's	$5.28
Cyanamid	Achromycin SF	250 mg cap	16's	5.28
Pfizer	Terramycin SF	250 mg cap	16's	5.28
Pfizer	Tetracyn SF	250 mg cap	16's	5.28
Cyanamid	Aureomycin SF	250 mg cap	100's	31.60
Cyanamid	Achromycin SF	250 mg cap	100's	31.60
Pfizer	Terramycin SF	250 mg cap	100's	31.60
Pfizer	Tetracyn SF	250 mg cap	100's	31.60
Cyanamid	Achromycin SF	Oral susp.	2 oz	2.64
Pfizer	Tetracyn SF	Oral susp.	2 oz	2.64
		Tetracycline-Antihistamines		
Cyanamid	Achrocidin	125 mg tablets	24's	4.26
Bristol	Tetrex APC	125 mg cap	24's	4.26
Pfizer	Tetracydin	125 mg tablets	24's	4.26
Cyanamid	Achrocidin	125 mg tablets	100's	17.04
Bristol	Tetrex APC	125 mg cap	100's	17.04
Pfizer	Tetracydin	125 mg tablets	100's	17.04
		Tetracycline-Nystatin		
Cyanamid	Achrostatin	250 mg cap	16's	5.60
Squibb	Mysteclin	250 mg cap	16's	5.60
Upjohn	Comycin	250 mg cap	16's	5.60
Cyanamid	Achrostatin	250 mg cap	100's	33.50
Squibb	Mysteclin	250 mg cap	100's	33.50
Upjohn	Comycin	250 mg cap	100's	33.50
Squibb	Mysteclin	125 mg cap	100's	17.23
Upjohn	Comycin	125 mg cap	100's	17.23

33. Retail fair trade agreements have been used at all relevant times by Cyanamid, Upjohn, and Squibb where such agreements are allowed by state law. Pfizer and Bristol, although not using written retail fair trade agreements with retailers, have managed to maintain resale prices identical to the fair trade prices. The retail prices maintained by respondents for sale to consumers are the list prices or a maximum of 10 percent under the list prices.

Pfizer and Cyanamid maintained wholesalers' resale prices on tetracycline, Aureomycin, and Terramycin by the use of fair trade agreements until 1956. These prices were identical with the prices retailers paid the respondents on direct purchases. Because of the Supreme Court's decision in *McKesson-Roberts* v. *United States*, 351 U.S. 305 (1956), holding illegal fair trade agreements between a manufacturer and competing customers, the respondents discontinued their fair trade agreements with wholesalers. Nevertheless, wholesalers' resale prices continued to be substantially noncompetitive with the prices at which the respondents sold these antibiotics directly to retailers. It was necessary that the wholesalers' resale prices be kept in line because the respondents' direct sales to retailers constituted a large part of their sales—an average among all respondents of 30 percent of total sales of tetracycline and 40 percent of sales in the prescription market itself.

34. Respondents' published prices to NPA hospitals (private hospitals) were consistently kept the same as the price to retailers, which as found above, was uniform at all times. NPA hospitals normally buy on a negotiated rather than a sealed bid basis. Unlike retail pharmacists, hospital pharmacists are not usually required to follow a brand specified on prescriptions and frequently order drugs by their generic name. Consequently, they generally ordered tetracycline as such rather than by brand name. Because of this method of buying, there was a great incentive for respondents to reduce the price in order to capture large spot sales. Any reduction in prices to an NPA hospital, however, might spread to a general NPA price reduction which, in turn, might bring about a price reduction in the prescription market because the price to retailers and the price to NPA hospitals were traditionally the same. The respondents in some instances gave free goods to NPA hospitals as a method of competition. Free goods were not shown on the invoices and the practice was utilized because it would not cause a decline in published prices.

The Commission finds that the use of free goods was employed as a means of preventing a general price reductions in the NPA market and in the retail market. Where NPA hospitals purchased tetracycline from local dealers, the respondents, other than Upjohn, gave a 10% handling allowance. The handling allowance was based on the published prices only, which, as found above, were identical.

35. CCS institutions (city, county, state hospitals) purchase tetracycline, Aureomycin, and Terramycin in two ways: by direct purchase and by formal bid procedures. Published prices to CCS institutions have been established and maintained at an identical level by all respondents, 16-2/3 off the price to retailers, and this is the price at which respondents did in fact sell tetracycline directly to CCS institutions. There has been only one significant price reduction in broad spectrum antibiotics to CCS institutions after October 1, 1951. Reductions on some tetracycline dosage forms, including the bottle of 100 250 mg. capsules, were made by Cyanamid and Bristol on May 3, 1955, and by Squibb the following day. Pfizer and Upjohn soon followed.

Where bids are called for, the respondents have established and maintained substantially uniform and identical prices. In most instances the prices used in bidding are the same as the published prices. Where bids were identical, the hospital would usually divide the order or rotate orders among the bidders in equal shares or draw lots.

A substantial quantity of bid awards went to dealers bidding as third parties. Dealer bidding had been a customary practice in the pharmaceutical industry. It was the custom or law in many places to give preference to local dealers in awarding bids, and most of the respondents at various times granted "handling allowances" of 10% or more off their CCS list price to retailers or wholesalers, Upjohn being the sole exception. The goods were then drop shipped to the hospital and the dealer was billed at the CCS list price less the handling allowance. Since respondents' list prices to retailers and, after May 1955, to wholesalers were higher than the CCS list price, the 10% discount permitted them to bid at or below the CCS list prices and still realize a profit. Upjohn for the brief period from September 24, 1956, to March 11, 1957, bid competitive prices to CCS hospitals, but on March 12, 1957, raised its price to the CCS list price.

The individual quantities involved in single CCS procurements on

the average are larger than purchases by NPA hospitals, wholesalers, and retailers. Because of the temptation on large bid invitations to shave prices in order to gain a short run lead over competitors' sales, there was a danger that such price reductions would spread to other sales, particularly in the prescription market. Submission of bids by local dealers tended to protect the respondents' published prices to all customer classifications by obscuring the origin and extent of any price reduction. Any price competition among dealers which was not encouraged by a respondent—which was the rule rather than the exception—cannot be considered respondents' price competition since the respondents in such cases granted a 10% discount from price lists which were identical.

36. The various Federal agencies that purchased tetracycline constituted as a group less than 10% of the over-all market. The Veterans Administration (VA) obtained its tetracycline requirements either one of two ways: (1) under a depot contract, which awarded formal bids and called for fixed amounts for VA depots situated across the country from which the VA distributed to its hospitals, or (2) under a decentralized bid arrangement whereby quotations of the respondents were distributed in schedule form to individual VA hospitals which purchased directly from the supplier. The VA hospital was not restricted to that schedule in purchasing, but could also use the General Services Administration (GSA) schedule. The GSA issued annually a "Solicitation for Offers" providing an opportunity for suppliers to submit price lists indicating prices at which they would offer their products to government agencies. The GSA procurement resembled the VA decentralized system in that bid invitations did not commit the GSA to purchase any specific quantity of drugs. The GSA "contract" as it is called included a most-favored-customer clause which required suppliers to extend to the GSA any lower prices offered to any purchaser, other than the Military Medical Supply Agency, on quantities between $25 and $5,000. The Military Medical Supply Agency solicited formal bids and the invitation constituted a commitment for the amount designated. The District of Columbia and the Public Health Service purchased directly from price schedules, by negotiation, and by formal bid procedures.

Cyanamid announced a Federal Government price of 16-2/3 plus 5 percent off the price to retailers on tetracycline. As each respondent entered the market its Federal price was set at a discount of 16-2/3 plus 5% off the price to retailers. The most important package

size and dosage form sold to the Federal Government was the bottle of 100 250 mg. capsules which initially had a uniform Federal price among all the respondents of $24.22. None of the respondents gave discounts based on the size of the order. The record shows that during the period covered by the complaint, once a new price was determined for a package size and dosage form, that price was adhered to with few exceptions regardless of the size of the order. This was true in all customer markets including the Federal market where the size of the orders ranged from 10 to 70,000 bottles.

The 16-2/3 plus 5% discount was continued until May 3, 1955, when both Cyanamid and Bristol announced a new Federal price of $19.58 on the bottle of 100 250 mg. capsules. The change was followed by Squibb, Pfizer, and Upjohn. Although each respondent initially followed the announced Federal price as described above, there were some instances in formal bids where deviations from the announced price occurred. Deviations were usually small, however, and were not consistently followed in later bids on the contracts. The record shows that the general level of Federal bids was artificially high. The MMSA, as late as 1958, had to pay $19.188 per bottle on an award for 45,072 bottles, while the Canadian Government was purchasing this bottle for $17.01 less 2% in 1955. Even though there were more deviations in prices in the MMSA market than in the other Federal markets, the magnitude of the price variations in the winning bid was usually small. Squibb, for instance, in December of 1957, obtained a substantial award on tetracycline capsules by giving the MMSA a .0004 cent reduction per bottle. The award amounted to $864,841 but the .0004 cent difference gave the government a reduction of only $18.03 from the former Federal price on such a quantity. By keeping the bid prices in line with the announced Federal price, the respondents were able to maintain a high price level not only in the Federal market but in all other customer markets.

Even in the MMSA market, where most of the price variations appeared, there resulted a spread of awards among the respondents in all MMSA awards up to June 1958, as follows:

Cyanamid	$1,083,958
Pfizer	951,298
Bristol	904,938
Squibb	864,841

(Upjohn did not normally attempt to sell to MMSA.) The pattern of substantially equal shares in the MMSA market among the four respondents listed did not change until June 1958, after the Commission's investigation of the respondents had commenced, when Pfizer

was the low bidder on an MMSA contract receiving an award of over $1,600,000.

37. The Veterans Administration received noncompetitive prices for fourteen months from June 6, 1955, to July 30, 1956. During this time there were six solicitations for bids by the VA. The bid prices submitted by all five respondents were identical except in the last two where Pfizer's bids were technically lower because they gave a bid of $19.188 net per bottle without a discount for cash payment, whereas the others gave a bid of $19.58 with a 2% cash discount if payment was made within 30 days—a difference of .0004 cents. The VA made only a partial award to Pfizer on these two bids. During this fourteen month period, the VA made repeated efforts to cause a break in the noncompetitive bidding. For instance, on the fourth bid, the VA drew names from a hat and made the award to Bristol. Procedures were established whereby only Bristol's tetracycline could be purchased by VA hospitals for the next six months. On the next solicitation of bids held six months later, the only change in bids was the Pfizer reduction of 0.0004 cents. This lack of significant price competition occurred even though the offer was for 28,992 bottles. As noted above, the VA made only a partial award of 9,600 because of the lack of price competition and the next month, on July 30, 1956, it asked for bids on 29,952 bottles and other items. Again identical prices were quoted except that Pfizer's bid was technically lower. Again the VA made only a partial award—this time a partial award of only 4,032 bottles. It was not until the next solicitation in October that there was significant price competition.

Sometime around March 15, 1955, a Cyanamid representative made a report concerning a bid award for tetracycline made to Pfizer by a CCS hospital. In his report he stated that Pfizer was undercutting Cyanamid "and everybody" on bid prices. He then stated: "This should be checked into and prices arranged as we have done on the V.A. setup." (CX 558 B.) It was soon afterwards, in June of 1955, that the fourteen month period of noncompetitive pricing commenced. In contrast to the $19.58 level in the VA market during 1955 and most of 1956, was the $17.01 price quoted by the respondents to the Canadian Government on the same bottle of 100 250 mg. capsules, during at least the period of August 1955 through November 1955.

38. The Commission finds as to the remaining Federal market that although there was some degree of price differences in the formal bids, this behavior is not inconsistent with out finding, *infra*, that a price conspiracy existed in the non-Federal markets. There is good reason why respondents should wish to confine their conspiracy to non-Federal prices. If the identity and uniformity of prices existed

in the Federal market to the degree it existed in the non-Federal markets, there was a greater risk of an antitrust investigation. By limiting the price fixing conspiracy to non-Federal customers and maintaining the appearance of price competition in the Federal market, the respondents would be diverting suspicion from themselves to some extent. Furthermore, the respondents must have realized that they could not continue identical prices for lengthy periods to Federal agencies in view of the efforts that could be made by such large buyers to bring about competitive prices—efforts of the nature that they encountered with the Veterans Administration.

39. The Commission also finds that during the period relevant to this action Cyanamid and Pfizer agreed on similar policies with respect to free samples to physicians (these free samples are to be distinguished from bulk free goods accompanying sales to hospitals).

On May 27, 1954, Cyanamid's Chicago Regional Manager wrote his Sales Manager:

> Apparently Pfizer and Roerig are *abiding* by reduction of samples because the number of calls from all reports from the field since my return from Absecon, have been practically none. (Emphasis added. Roerig was the Pfizer division handling sales of tetracycline.) (CX 593 B.)

On June 17, 1954, the same Regional Manager wrote:

> Within the last thirty days, complaints from the field regarding the Pfizer and Roerig operations have been practically nil. From all indications, it is presumed that these competitors are *adhering to the operation that was reported by Mr. Wendt at the Regional Managers meeting.* (Wendt was Cyanamid's Director of Sales. Emphasis added.) (CX 594 A.)

About *one year later*, on July 8, 1955, this Regional Manager wrote in regard to furnishing free tetracycline to doctors for clinical use to Michael Reese Hospital in Chicago:

> Approximately *one year ago*, we were furnishing the same institution material for clinic use through Dr. Kagan, Chief of Pediatrics. This procedure was stopped *due to a report by Pfizer* to Mr. Wendt. (Emphasis added.) (CX 595.)

40. As hereinbefore noted, Bristol, Squibb and Upjohn hoped to obtain a license under any tetracycline patent that might issue to Pfizer and, knowing that such a patent would be of doubtful validity, had reason to believe that Pfizer might grant licenses rather than sue for infringement. Bristol also had good reason to believe that Pfizer would be more inclined to grant such licenses if it could be assured that the licensees would maintain the price of tetracycline at the existing level. A Pfizer official had already expressed disapproval of Squibb as a possible bulk customer of Bristol, since Squibb was

considered by Pfizer to be a "price cutter." Bristol had previously adopted the tetracycline price schedules of Cyanamid and Pfizer, and Squibb and Upjohn also adhered to the same price level when they entered the market on September 17 and October 11, 1954, respectively. Documents prepared by Squibb and Upjohn employees shortly after these firms began selling the product compel the conclusion that they had agreed with Bristol not to cut the price of tetracycline. On September 17, 1954, the day Squibb began marketing its tetracycline product, Steclin, the Squibb Manager of Marketing, Heberger, sent the following message to all representatives of his firm:

> The Steclin pricing schedule must be adhered to strictly. Steclin is not to be involved in any special terms used to meet competitive situations on other antibiotic products.
>
> Steclin should be sold direct in every case possible. When handling credit situation must apply we will arrange 10% handling credit only on a drop shipment basis.
>
> We have had some reports of competitive prices of Tetracycline products at variance with published schedules. Please send along to your branch promptly any specific information regarding such deviations you run into on your territory. (CX 204.)

On October 13, 1954, Heberger informed Squibb's Atlanta branch manager by telegram that "Squibb cannot be officially connected with any price maneuver on Steclin which can be construed as cutting the price. There can be no compromise with our position of maintaining prices on this product." (CX 207.) On November 12, 1954, all of Squibb's field managers were informed by an official that "* * * it is our fixed policy not only to avoid price cutting on Steclin but to avoid any practice which might lay us open to such an accusation." (CX 210). On April 27, 1955, the following letter was written by Heberger:

> I was disturbed to learn that we were the successful bidder to Los Angeles County because we bid on Tetracycline 250 Mg. capsules $22.49 per 100 less 2% discount. It is nice to get a Steclin order finally from Los Angeles County but I have my fingers crossed, anticipating certain reactions to what we did, which may not be good.
>
> * * * * * * *
>
> As I say, it would be nice to get the order but I am hoping there are no serious results. (CX 213.)

On August 19, 1955, the assistant manager of Squibb's marketing department wrote the following letter to a sales representative:

> We are well aware of the problem that you are confronted with on the Tetracycline quotations. We too want the bid at King County for the 10,000 250

Mg., but under no circumstances can we give you authority to quote less than $22.49 per 100.

You may of course allow a 10% handling allowance to the Northwest Medical Supply less the usual 2% cash discount. If they are inclined to pass this handling allowance on down I don't think we can do anything about it, however, it would be inadvisable for you to suggest this arrangement, particularly in writing. (CX 217.)

On April 6, 1955, Upjohn's Los Angeles, California, branch manager wrote the following letter to Upjohn's Price Determination Department manager concerning a low bid by Squibb:

As requested, we are enclosing the results of the bids at Los Angeles County Hospital:

864 Tetracycline Caps. 250 Mg. went as follows:

Pfizer	$22.49 2% 15th proximo.
Squibb	22.49 2% open.
Lederle	22.49 net.
Bristol	22.49 net.

Homer Hammond feels Squibb will get the bid with an open 2% time limit * * *.

* * * * * * *

We will forget that one. On the Panmycin it looks like Squibb scuttled our ship. I wonder if Bristol will complain to them as they did with us. (CX 473.)

The following document, undated and unsigned, concerning Bristol's transactions during the summer of 1955 was obtained from Squibb's files: (CX 308.)

Bristol Price Variations

1. Yants Pharmacy, Bakersfield, Calif. State of California bid.	19.76 unauthorized.
2. Santa Clara County Hospital [thru small dealers].	20/100 free—probably correct.
3. Boston Division	20/100 free—correct; 1 case 25/100 free—not likely to repeat.
4. Lebanon Hospital, Bronx	100/500 free, yes.
5. Cost of free goods and samples	7.5%—7 months.
6. Jefferson Hospital, Phila	1/1 free—Boly. Susp.—mistake.
7. Mark Surgical Supply for University Hospital, Augusta, Ga.	22.49 less 10%—problem acct.
8. New York Eye & Ear Dispensary	20% in free goods—yes.
9. Johns Hopkins	Report of $17.40 through dealer—checking.

Opposite each of the above items is an explanation of the "price variation." Since it is highly unlikely that a Squibb employee could furnish all explanations or answers set forth in the document, the Commission concludes that such data came from Bristol.

On November 22, 1955, Richard Anderson, Director of Sales of Bristol Laboratories received a letter from the Director of Sales of Cyanamid. This letter was found by Federal Trade Commission attorneys in Bristol files in a mutilated condition with the letterhead and the sender's name torn off. The letter reads:

11/22/55

Dear Dick:

I am enclosing the most recent prices on all of our Achromycin prices, together with what we call a Trade Class chart. This Trade Class chart is our standard procedure for classifying accounts for our Lederle Purchase Plan and our handling charge policy.

Our branches are instructed to follow this chart with great precision. Basically, except for the subject of our discussion Friday afternoon, there are no deviations. I might say that the branch offices do not report to the Sales Department but rather to the Treasurer's Office, so that the opportunity for special situations is non-existent.

Our Dominion price for 250 Mg. capsules has been and will continue to be $17.01. This price applies to the Department of Defense Production and the Department of Veterans Affairs. Our price to the Canadian Provincial Departments is $25.50.

The name of the hospital survey group is Davee, Koehnlein & Keating at One North LaSalle Street, Chicago, Illinois.

Sincerely, (CX 328.)

On December 16, 1955, Squibb's Manager of Marketing sent a letter to a sales representative in regard to a bid of Achromycin, Cyanamid's tetracycline product sold through its Lederle Laboratories Division. The letter stated in part:

On Bid No. 635 for 100's of tetracycline 250 Mg. Lederle's product was offered at $21.08 per 100. In order to properly record this violation I must know whether this was a direct bid by Lederle, or whether the bid was made through a dealer. (CX 220.)

The bid in this letter was made to a hospital either by Lederle or by a retail dealer. As heretofore described, retail dealers were often given a 10 percent handling allowance by most of the respondents to allow them to bid to hospitals. The respondents submitted their own bids at the regular CCS prices and it was always possible that a dealer would bid below the CCS price and win the award. If this

occurred it would not represent a price cut by a respondent as long as the dealer was given the usual 10 percent handling charge. The above letter clearly indicates that a bid below the regular CCS price by Cyanamid, rather than a dealer, would constitute a "violation" and would be "recorded."

In what appears to be sales manager's report, a Cyanamid representative stated on July 30, 1955:

If Pfizer is trying to hold the price line, would it be helpful to collect some copies of bids showing the low-cut bids by Pfizer's accounts so that Pearl River could show them to Pfizer officials? (CX 597 B.)

41. The Commission finds from the circumstances and the documentary evidence of record, particularly, but not limited to, those documents designated above, that respondents gave each other assurances on tetracycline prices which amounted to express and implied agreements that they would maintain the price of their products at the level which broad spectrum antibiotics had been sold since October 1951. These agreements extended to sales in the prescription and CCS and NPA markets. The Commission further finds that respondents agreed to submit identical bids to the Veterans Administration beginning June 6, 1955. This agreement continued and was adhered to until after July 30, 1956, when it was made clear to the respondents by the Veterans Administration's actions that identical pricing would have to be abandoned. These agreements constitute unfair methods of competition and unfair acts and practices in the sale and distribution of tetracycline in interstate commerce.

42. The Commission concludes from the facts set forth herein that Pfizer knowingly made false and misleading statements of fact before the Patent Office and deliberately suppressed information, all of which was material to the Patent Office's consideration of its application for a patent on tetracycline. The Commission finds that the obtainment and subsequent assertion of rights and privileges by Pfizer under its tetracycline patent, U.S. Patent 2,699,054, constitute an unfair method of competition and unfair act and practice within the meaning of the Federal Trade Commission Act.

43. The Commission concludes from the facts set forth herein that Cyanamid accepted a license under said patent with knowledge that it had aided Pfizer in securing the patent by reason of its misrepresentations of fact to, and its withholding of information from, the Patent Office.

44. The tendency, capacity, and effect of the conspiracy entered into and maintained by respondents Pfizer, Cyanamid, Bristol, Squibb and Upjohn in the manner aforesaid, the acts and practices performed thereunder and in connection therewith, as set out herein, and the individual acts and practices of Pfizer and Cyanamid as found herein, have been and are substantially to hinder, lessen, restrict and restrain competition in the sale of tetracycline in, among and between the several states of the United States and in the District of Columbia; to prevent price competition among respondents in the sale of said products; to foreclose markets and access to markets to competitors in the sale and distribution of said products; and to create a monopoly in the sale of tetracycline.

The above acts and practices have also had the effect of preventing competition of tetracycline with the other broad spectrum antibiotics, including Aureomycin and Terramycin.

CONCLUSIONS

1. The Federal Trade Commission has jurisdiction of this proceeding, of the respondents, and of the acts and practices of the respondents.

2. The aforesaid acts and practices of the respondents constitute unfair methods of competition and unfair acts and practices in commerce within the intent and meaning of the Federal Trade Commission Act.

3. This proceeding is in the interest of the public.

Commissioner Anderson concurring in part and dissenting in part. Commissioner Elman's position in this case is set forth in a separate opinion.

Progress of Applications Before the Patent Office

	October 1953	November 1953	December 1953	January 1954	February 1954	March-September 1954
Conover application (Pfizer). Parent application filed Oct. 23, 1952, for Tetracycline and deschlorination process.	Oct. 29, Patent Examiner issues notice to copy process claim for proposed interference on Tetracycline and deschlorination process.	New claim added as suggested.	Dec. 28, Patent Examiner declares the first interference (between Conover and Boothe-Morton).	Exchange of proofs between Pfizer and Cyanamid. Cyanamid concedes priority to Pfizer.	----------	Mar. 2, Patent Examiner declares second interference on Tetracycline Hydrochloride. Numerous motions filed by all three parties. Pfizer seeks termination of interference and files affidavit that it is losing $50,000 a month in royalties because of delay.
Boothe-Morton (Cyanamid). Application filed Mar. 16, 1953, for Tetracycline and deschlorination process.	Oct. 29, Patent Examiner issues notice to copy claims for proposed interference	New claims added. Nov. 16, Edelblute has interview with examiner who inquires about inherent production.	Statement filed by Edelblute (received on Dec. 7) denying coproduction. Dec. 28, first interference declared.	----------	Feb. 12, Patent Examiner rejects claims as a result of the concession by Cyanamid in the first interference. Application eventually abandoned.	
Minieri (Heyden-Cyanamid). Application filed Sept. 28, 1953, for Tetracycline and fermentation process.	Oct. 29, process claim rejected on basis of inherent production in Duggar patent. Notice of proposed interference.	Nov. 4, Cyanamid purchases Minieri application.	Dec. 14, Edelblute appointed attorney.	----------	Feb. 19, Patent Examiner suggests for purposes of an interference a claim for Tetracycline Hydrochloride. (Claim was added).	Second interference declared. Cyanamid seeks to persuade examiner to dissolve interference on the ground that Tetracycline Hydrochloride is not patentably distinct over the base. Edelblute again denies that Tetracycline was inherently produced in prior art.

1747

Findings

Martin-Bohonos (Cyanamid). Application filed Oct. 15, 1953, for Tetracycline and fermentation process.			Dec. 11, Patent Examiner rejects process claims as unpatentable over Duggar & Niedercorn.			
Heinemann (Bristol). Application filed Oct. 19, 1953, for Tetracycline and fermentation process.			Dec. 8, Patent Examiner rejects both process and product claims on the assumption of inherent production in Duggar & Niedercorn.	Jan. 15, continuation-in-part application filed on Tetracycline salts and process. Affidavit filed alleging the Hydrochloride to have unexpected qualities over the base.		Second interference declared as to continuation application. Parent application rejected on basis of Stephens article. No rejection on basis of inherent production. Bristol seeks to delay second interference by dilatory tactics.
Bogert-Walsh (Pfizer). Application for process of recovering Tetracycline from fermentation broth filed Apr. 14, 1954.					Feb. 3, counsel files argument that Duggar & Niedercorn are not prior art against applicant's claims. Feb. 8, Patent Examiner rejects process claims as unpatentable over Duggar & Niedercorn & Sobin patents. Suggests Tetra. Hydrochloride for interference. No mention of a speculation of inherent production.	
Tanner (Pfizer). Application filed Nov. 12, 1953, for fermentation process.	(No Office action until July 1954).					July 20, Patent Office rejects process claims on inherent production.

Progress of Application Before the Patent Office—Continued

	October 1954	November 1954	December 1954	1955	
Conover application (Pfizer). Parent application filed Oct. 23, 1952, for Tetracycline and deschlorination process.	Oct. 14, Patent Examiner rules on all motions, dissolves interference on lack of patentable distinction of Tetra. Hydrochloride over the base. Also rules that Tetracycline and its Hydrochloride are unpatentable over the disclosures of Duggar & Niedercorn which apparently produced Tetracycline along with Chlortetracycline. Patent Examiner reopens Heinemann parent application and adds inherent production as ground for rejection.	Nov. 24, Patent Examiner rejects product claims in ex parte proceeding on basis of inherent production in Duggar & Niedercorn. Nov. 29, conference with Patent Examiner.	Dec. 8, Tanner & Bogert affidavits filed. Dec. 9, supplemental affidavit filed. Patent Examiner allows claims.	Jan. 11, Patent issued. Pfizer files infringement action against Bristol, Squibb, and Upjohn.	
Boothe-Morton (Cyanamid). Application filed Mar. 16, 1953, for Tetracycline and deschlorination process.					
Minieri (Heyden-Cyanamid). Application filed Sept. 28, 1953, for Tetracycline and fermentation process.		Nov. 24, ex parte rejection of product claims on basis of inherent production.		Cyanamid eventually receives Patent No. 2,734,018, on process claims as an improvement patent over Duggar & Niedercorn.	

1747

Findings

Martin-Bohonus (Cyanamid). Application filed Oct. 15, 1953, for Tetracycline and fermentation process.					
Heinemann (Bristol). Application filed Oct. 19, 1953, for Tetracycline and fermentation process.		Nov. 24, ex parte rejection of product claims on basis of inherent production.	Heinemann begins tests to prove that Tetracycline is present in the production of aureomycin.		Bristol abandons product claims in all applications
Boggert-Walsh (Pfizer). Application for process of recovering Tetracycline from fermentation broth filed Apr. 14, 1954.		Nov. 2, Patent Examiner rejects claims as unpatentable over a prior art process. Patent Examiner speculates that Duggar process inherently produces Tetracycline.			May 4, Hutz argues that Tetracycline was not an impurity in Duggar fermentation. "Patent Office is now aware that inherent production is not in fact true."
Tanner (Pfizer). Application filed Nov. 12, 1953, for fermentation process.				Jan. 20, Hutz states that Tetracycline was first produced by deschlorination.	
				Jan. 5, Patent Office division receives Taylor affidavit. Jan. 21, another Heinemann application rejected over Duggar & Niedercorn.	

OPINION OF THE COMMISSION

AUGUST 8, 1963

INDEX

By HIGGINBOTHAM, *Commissioner:*

The complaint in this matter charges respondents with unfair methods of competition and unfair acts and practices in commerce in violation of Section 5 of the Federal Trade Commission Act. The hearing examiner held in his initial decision that the evidence failed to establish that respondents had engaged in any of the violations alleged in the complaint. The matter is now before the Commission on the appeal of counsel supporting the complaint from this decision.

In substance, the complaint alleges that Pfizer engaged in unfair methods of competition in the production and sale of antibiotics in that it unilaterally attempted to monopolize the antibiotics industry, attempted to and did monopolize the tetracycline industry, made false, misleading and incorrect statements for the purpose of inducing the United States Patent Office to grant a patent on tetracycline and caused said patent to be issued as a result of such misrepresentations; and independently thereof, caused the patent to issue although the product was unpatentable as a matter of law; and issued invalid licenses under said patent. The complaint further alleges that respondents by conspiracy fixed the prices of tetracycline, chlor-

tetracycline (Aureomycin) and oxytetracycline (Terramycin); foreclosed and prevented competition in tetracycline and chlortetracycline by licenses and cross-licenses; attempted to and did monopolize tetracycline; Pfizer, Bristol and Cyanamid withheld material information from the Patent Office as a result of which Pfizer was enabled to secure the tetracycline patent; and Pfizer issued and Cyanamid, Bristol, Olin Mathieson Chemical Corporation (hereinafter referred to as Squibb), and Upjohn accepted licenses under the tetracycline patent with knowledge that material information was withheld from the Patent Office by at least one of the applicants for a tetracycline patent, and independently thereof, with knowledge the product was unpatentable.

Counsel supporting the complaint have taken exception to numerous findings and conclusions made by the hearing examiner with respect to the alleged agreements among respondents and with respect to the alleged misrepresentations to, and withholding of information from, the Patent Office. They have not, however, argued that it is necessary that the commission render a legal opinion as to the patentability of tetracycline.

I

SUMMARY OF HOLDINGS

Shakespeare said "Brevity is the soul of wit".[1] Judging from the length of this opinion, and the separate findings of fact, some might infer that his admonition has gone unheeded. But here we are confronted with a record of over 11,000 pages, exhibits of approximately 8,000 pages, briefs totalling thousands of pages, and two full days of oral arguments on appeal before the Commission. Moreover, to some extent this opinion probes the arcane topic of antibiotic research. This antibiotic broth is spiced with the law of patents and unfair methods of competition. And so, out of a consideration for the rights of all the parties, we have set out in detail the breadth of their major contentions. However, for the sake of brevity, we are summarizing below our principal holdings which will be developed in greater detail in subsequent sections:

1. With respect to tetracycline this Commission is not passing on the issue of its patentability under the patent statutes and law. But this Commission holds that its jurisdiction extends to preventing the *enforcement* of a patent procured by unfair methods.

2. We hold that Pfizer by making certain representations and misrepresentations, and withholding other information, prevented the

[1] Hamlet, Act II, Scene 2, Line 90.

patent examiner from making an accurate appraisal of the patentability of tetracycline. Misrepresentations and the intentional withholding of material information to obtain a commercially valuable patent is an unfair method of competition and an unfair act or practice.

3. We hold that Pfizer engaged in such an unfair method of competition and unfair act or practice.

4. With respect to Cyanamid's and Pfizer's conduct before the Patent Office, there is evidence in the record which would allow us to draw the inference that Cyanamid and Pfizer conspired in the commission of this unfair method of competition. There is also evidence in the record from which a contrary inference may be drawn.

While "the possibility of drawing either of two inconsistent inferences from the evidence does not prevent the Commission from drawing one of them," [2] on balance as fact finders we neither exonerate Cyanamid and Pfizer nor do we find the case against them *on the issue of conspiracy before the Patent Office* proven by substantial, reliable and probative evidence, on the record as a whole. Thus the conspiracy charge before the Patent Office as to Cyanamid and Pfizer is simply "Not Proven".

5. However, as to the proceedings before the Patent Office, we hold that Cyanamid made misrepresentations to and withheld material information from the Patent Office. The type of information withheld was similar to that withheld by Pfizer. Thus, knowing the materiality of the information withheld, and knowing that this failure to reveal to the Patent Examiner would increase the probability of a patent issuing to someone, its receipt of a license under the Conover patent and the exercise of the rights granted thereunder, set the stage for the subsequent enactment of the price fixing conspiracy in which Cyanamid played a major role.

6. We hold that Bristol did not engage in any unfair methods of competition before the Patent Office.

7. We hold that neither Squibb nor Upjohn engaged in any unfair methods of competition before the Patent Office.

8. We hold that Pfizer, Cyanamid, Bristol, Squibb and Upjohn engaged in a conspiracy to fix, maintain and stabilize the price of tetracycline.

9. Moreover, we hold that the totality of Pfizer's conduct amounts to a separate unfair method of competition, the basic purpose of which was to restrain trade in the sale and distribution of tetracy-

[2] *Giant Food, Inc. v. Federal Trade Commission*, D. C. Cir., Slip Opinion, p. 14 (June 13, 1963) [7 S.&D. 710, 720].

cline. Its unfair conduct before the Patent Office set the stage for its subsequent actions and the later conspiracy of all the respondents. Moreover, its pricing practices aggravated and perpetuated the initial unfair method of competition. In sum, its conduct represents an unbroken chain of anti-competitive tactics which constitute a continuing unfair method of competition.

We are fully cognizant of the emphasis placed by the courts on the opportunity of hearing examiners to observe the demeanor of witnesses in order to appraise the credibility of their testimony. *Universal Camera Corp* v. *NLRB*, 340 U.S. 474 (1951). See also *FCC* v. *Allentown Broadcasting Corp.*, 349 U.S. 358, 364 (1955). However, our findings and conclusions on the question of misrepresentation and withholding information from the Patent Office are based on undisputed evidence and the testimony of expert witnesses. We feel it our duty, nevertheless, to set forth in detail exactly why the hearing examiner's reasoning and interpretation of the evidence cannot be accepted. And as to the price-fixing charge, we shall explain in detail exactly why the hearing examiner's reasoning and interpretation of the evidence cannot be accepted. And as to the price-fixing charge, we shall explain in detail our disagreement with the hearing examiner's interpretation of the record.

II

SCIENTIFIC BACKGROUND

This case involves the obtaining of a patent on tetracycline, one of the most important of the "broad spectrum" antibiotics. The annual sale of tetracycline has at least on one occasion exceeded the figure of one hundred million dollars. Besides tetracycline, the broad spectrum antibiotics include the following: chlortetracycline, sold under the name of Aureomycin; oxytetracycline, sold as Terramycin; and chloramphenicol, sold under the name of Chloromycetin. The earlier antibiotics such as penicillin and streptomycin are known as "narrow spectrum" antibiotics because they are normally effective against either gram-positive or gram-negative bacteria, but not both. "Broad spectrum" antibiotics are effective against both kinds of bacteria, as well as various other pathogenic organisms, and are for that reason commonly referred to as "the wonder drugs." Most of the antibiotics, including tetracycline, are fermentation products of particular microorganisms in aqueous nutrient media. The medium is inoculated with the microorganism and under controlled and aseptic conditions the microorganism is allowed to grow. The antibiotic or antibiotics

produced are recovered, processed, and packaged in dosage forms. Tetracycline can also be produced by deschlorination of Aureomycin, *i.e.*, by subjecting Aureomycin to a process of mild catalytic hydrogenation to remove the chlorine atom from the Aureomycin molecule. This chemical transformation was the original method by which tetracycline was discovered.

Various patents are held by respondents on the broad spectrum antibiotics. These patents cover not only the processes for making the antibiotic, but also the antibiotic product itself. If a patent is obtained on a basic antibiotic product, the patentee has the legal right to exclude all others from making or selling this product and even from using this product in the manufacture of a completely different antibiotic. 35 U.S.C. Sec 271(a). The basic patents on the broad spectrum antibiotics are set forth in the following paragraphs. It should be emphasized that there are many related patents not mentioned covering improved processes and recovery methods.[3]

The patent covering Aureomycin is the Duggar patent issued to Cyanamid on September 13, 1949. The Niedercorn patent, issued September 2, 1952, to Cyanamid, is an improvement patent on the Duggar fermentation process. No company has been licensed to sell Aureomycin, although Bristol obtained a limited license from Cyanamid to produce Aureomycin in amounts up to 6% in the manufacture of tetracycline. This license was granted in settlement of a patent infringement suit commenced by Cyanamid against Bristol. Pfizer has a license to produce Aureomycin for the manufacture of tetracycline by the deschlorination method.

Pfizer owns the Sobin patent which covers both Terramycin and the fermentation process for making Terramycin. Pfizer has licensed no company to manufacture or sell this product.

Pfizer also owns the Conover patent on the product tetracycline and the deschlorination process for making it. As a result of a cross-licensing agreement negotiated by Pfizer and Cyanamid in settlement of an interference proceeding in the Patent Office, Cyanamid has a license under the Conover patent to manufacture and sell tetracycline. Bristol obtained a license to manufacture and sell tetracycline in settlement of an infringement suit filed by Pfizer. As part of the same settlement, Squibb and Upjohn obtained a license from Pfizer to sell tetracycline to the "drug trade."

Cyanamid's basic Aureomycin patents, the Duggar and Niedercorn patents, are in the record as Commission Exhibits 1 and 2. It is

[3] According to a tabulation contained in the F.T.C. Economic Report on Antibiotics Manufacture, June 1958, p. 235, as of 1956, there were 14 United States patents relating to tetracycline, 16 patents relating to Aureomycin, 3 patents relating to Terramycin and 36 patents relating to Chloromycetin.

stated at the beginning of the disclosures of the Duggar patent that "* * * one of the objects of the present invention [is] to describe a new antibiotic substance which is highly effective against Gram negative bacteria. Not only is the new antibiotic of the present invention active against Gram negative organisms of a large number and wide variety, it is also active against many of the common pathogenic Gram positive bacteria. Accordingly, a further object of the invention is to provide a substance possessing bacteriostatic or bacteriocidal activity against pathogenic organisms of both the Gram positive and Gram negative groups."

The molecular structure of this "antibiotic substance" which Duggar called Aureomycin was not known at the time the Duggar patent was issued. Therefore, it was necessary to describe it by obeserved characteristics including certain chemical properties, the refractive indices of crystals, and characteristic spectroscopic absorption bands in the ultra violet and infra red ranges of the spectrum. Later research has shown that when following certain procedures, the resultant product is actually composed of two different antibiotics which are now technically referred to as chlortetracycline and tetracycline, with the tetracycline usually constituting something less than ten percent of the antibiotic substance. The Duggar patent goes on to describe the microorganism which was found to have produced Aureomycin, stating that it was isolated from a soil sample taken from a timothy field in Missouri and that a sample of the organism had been deposited with the Fermentation Division of the Northern Regional Research Laboratory at Peoria, Illinois, and given the identifying number of NRRL–2209. The Duggar patent states that this microorganism differs from any previously described species and proposes to name it *Streptomyces aureofaciens*. Then follows a description of a means of producing Aureomycin by growing a culture of *S. aureofaciens* in a nutrient medium under prescribed conditions of time, temperature, pH and other conditions. Duggar explains that various processes relying upon physical and chemical properties of Aureomycin may be devised for recovering it from the fermentation liquor and sets forth a recovery method that was described in another pending patent application. This recovery method is commonly referred to as the Pidacks Florisil-column recovery method.

Cyanamid's Niedercorn patent, as noted before, covers an improved fermentation process for making Aureomycin. This patent refers to the Duggar patent and states that:

> An object of this invention is to provide a process whereby the production of and yield of the antibiotic known as aureomycin may be improved. * * * It is a further object to produce a fermentation medium in which tap water may

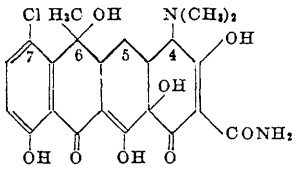
be used, in which a cation is introduced which will cause the aureomycin produced to be present in an insoluble form, and in which the pH is controlled or controllable within a range in which the yields are particularly satisfactory.

The patent further states that for maximum growth, it is necessary that the pH of the fermentation medium be controlled within rather narrow limits and that the pH of the fermentation must be stabilized. The patent then describes some 44 specific examples of media to be used with instructions as to how the fermentation should be conducted.

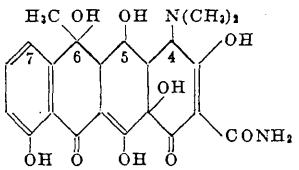
During 1952, a Pfizer research team of scientists ascertained the chemical structure of Aureomycin and Terramycin. Doctors L. H. Conover, C. R. Stephens, and R. B. Woodward of Harvard University, among others, were members of this team. The structures of Aureomycin and Terramycin proved to be very similar. Both consisted of a group of 4-rings illustrated below, the difference being that Aureomycin at position 7 possessed a chlorine atom, but did not have a hydroxyl group at position 5. The converse was true in Terramycin, namely, a hydroxyl group appeared at position 5 whereas at position 7 there was no chlorine atom.

The structures of Aureomycin, Terramycin, and tetracycline are:

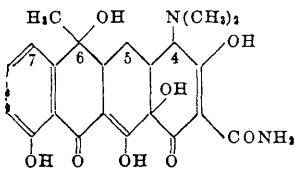
AUREOMYCIN
(CHLORTETRACYCLINE)



TERRAMYCIN
(OXYTETRACYCLINE)



TETRACYCLINE



Dr. Conover speculated that it might be possible to develop an antibiotic by removing the chlorine atom from Aureomycin. He speculated that such an antibiotic might have qualities superior to Aureomycin and Terramycin. Dr. Conover succeeded in making this antibiotic in June of 1952 by hydrogenating Aureocycin, a process of replacing the chlorine atom with a hydrogen atom.

In October of 1952, an article (referred to herein as the "Stephens article") authored by the Pfizer research team was published by the *Journal of American Chemistry* disclosing the structures of Aureomycin, Terramycin, and tetracycline, although it was not disclosed how tetracycline could be made. In view of the similarity of the structures of these three compounds, Aureomycin and Terramycin were given the generic names of chlortetracycline and oxytetracycline.

III

TETRACYCLINE PATENT APPLICATIONS BY THE RESPONDENTS

A. *PFIZER*—On October 23, 1952, the Conover application for a patent on tetracycline and the deschlorination process was filed by Pfizer with the Patent Office. On July 23, 1953, the Patent Office rejected the product claims in the Conover application on the ground that the subject matter was obvious in the light of the Duggar and Sobin patents because of the similarity of the structural formula of tetracycline to Aureomycin and Terramycin. On October 20, 1953, Pfizer filed an amendment to its patent application pointing out that the structures of Aureomycin and Terramycin were not known at the time of Conover's discovery of tetracycline. Thereafter, the patent examiner, Lidoff, withdrew the aforementioned ground for rejecting the Conover claims.

Pfizer entered the race for a patent on the fermentation process by filing the Tanner application on November 12, 1953. Tanner alleged in the application that a new strain of Streptomyces, unidentified as to species, was used in the process.

B. *CYANAMID*—As a result of the indication in the Stephens article of the probable existence of tetracycline and its structure, other companies began experimenting and discovering ways of making it. On March 16, 1953, Cyanamid filed its Boothe-Morton application for a patent on tetracycline and a process for manufacturing it by deschlorination of Aureomycin.

Cyanamid scientists were also at work on a fermentation process and discovered that it could be made by using certain strains of *S. aureofaciens* with the use of a medium with a low chloride ion concen-

tration. On October 15, 1953, Cyanamid filed its Martin-Bohonos application for a tetracycline fermentation process.

C. HEYDEN—On May 29, 1953, Dr. Minieri of the Heyden Chemical Corporation produced tetracycline by fermentation and filed application for a patent on September 28, 1953. This was apparently the first discovery that tetracycline could be made by direct fermentation. The application stated that the process used a newly discovered microorganism and mutants thereof and that the fermentation media were substantially free of chlorides. On October 1, 1953, Heyden publicly announced its discovery.

On October 27, 1953, Minieri's attorney filed a request for an interference on tetracycline, stating that he had reason to believe that there were two other similar applications pending. On October 29, 1953, patent examiner Lidoff rejected process claims in the Minieri application as lacking invention over the Duggar fermentation process. He stated:

> The production of tetracycline as well as varying amounts of aureomycin (chlortetracycline) would appear to be inherent in the process of Duggar, whose claims are not restricted solely to the production of aureomycin (chlortetracycline). There is found no patentable invention in culturing Duggar's mutants under the same conditions and finding that tetracycline as well as chlortetracycline is produced.

The product claims were rejected on the basis of the Stephens article which had described the structure of tetracycline before the date of Minieri's application. Examiner Lidoff notified Minieri that to be entitled to a product claim for interference purposes, Minieri would have to show that his discovery was made before the date of the Stephens article. At the same time, Lidoff issued notices to Pfizer (Conover) and Cyanamid (Boothe-Morton) to copy claims for a proposed interference on tetracycline and the deschlorination process.

Early in November, Cyanamid acquired the Minieri application along with its purchase of Heyden's Antibiotic Division. Harvey Edelblute, Cyanamid house counsel, eventually became the attorney handling the Minieri application. On November 16, 1953, Edelblute had an interview with Lidoff who inquired about the possibility that tetracycline may have always been concomitantly produced by Cyanamid in its production of Aureomycin. Edelblute filed a statement in December 1953, assuring the examiner that Cyanamid had investigated the matter and had determined that coproduction did not occur. Later in December a Cyanamid scientist ascertained that commercial Aureomycin contained some tetracycline. (CX 81.)

D. *BRISTOL*—Bristol in the meantime had discovered that earlier experimental fermentation work it had done, which had been abandoned, probably produced tetracycline and on October 19, 1953, Bristol filed the Heinemann application for a patent on the product tetracycline and on a fermentation process. Heinemann described the microorganism used as a new species of microorganism and tentatively called it Streptomyces BL 567201.

On December 8, Lidoff rejected both the process and product claims in Bristol's Heinemann application on the assumption that inherent production of tetracycline occurred in the Duggar and Niedercorn processes, in which case tetracycline and the Heinemann fermentation process would lack novelty and could not be patented. He ruled:

> Claims 8 to 17 are rejected as lacking invention over each of Duggar and Niedercorn, particularly when considered in the light of the J.A.C.A. publication. Each of these patentees shows a process of producing a mixture of antibiotics having the same basic formula as that proposed by applicant, which comprises growing a Streptomycete and mutants thereof under controlled conditions. Applicant's species may be a mutant of the species used by patentees. It is recognized that different mutants produce different proportions of the tetracycline antibiotic, depending in part upon strain and upon media. The media of both applicants and patentees comprise a nitrogenous and carbohydrate containing aqueous solution. Culture is carried out under submerged aerobic conditions until substantial antibiotic activity is imparted to said solution, and the antibiotic is recovered from the broth. The temperature and duration of the fermentation of both patentees and applicants come within the same range. Neither the private collection number of the organism nor the arbitrary name assigned to the product serve to distinguish patentability over the process of patentees.
>
> Product claims 1 to 7, 18 to 20 are similarly rejected as being unpatentable over each of Duggar and Niedercorn since it appears, from the processes thereof, that applicant's product must be produced inherently. The claims read on the product in any environment (see In re Kebrich 671 O.G. 597 and Parke, Davis v. Mulford, 189 F. 95).[4]

A similar statement as to inherent production was made a few days later when the same patent examiner rejected the process claims in Cyanamid's Martin-Bohonos application.

On January 15, 1954, Bristol divided out some of its claims in the Heinemann application and placed them in continuation-in-part applications. One of these applications contained claims for tetracycline salts, and an affidavit by a Bristol scientist filed with the application contained statements to the effect that the salts had unexpected qualities over the free base. The purpose of the affidavit was

[4] Commission Exhibit 9, p. 31. The product claims were also rejected on the ground that the Stephens article constituted a statutory bar, since under 35 U.S.C. 102(b) it was published more than one year before the date of Heinemann's application.

to support Heinemann's contention that the description of the free base in the Stephens article would not bar a claim for certain salts such as tetracycline hydrochloride.

On February 8, 1954, the examiner rejected the process claims in Heinemann's continuation-in-part application as being unpatentable over the analogous processes of Duggar, Niedercorn, and Sobin. No mention was made, however, that the examiner based this rejection on the ground that tetracycline was coproduced in these fermentations. He also notified Heinemann that he proposed to declare an interference on tetracycline hydrochloride.

IV

THE FIRST INTERFERENCE

On December 28, 1953, Lidoff declared an interference (referred to herein as the "first interference") on tetracycline and the deschlorination process. The interference was between Pfizer's Conover application and Cyanamid's Boothe-Morton application. Pfizer and Cyanamid entered into an agreement looking toward an amicable settlement of this interference. The parties agreed to exchange proofs as to priority of invention of tetracycline. The agreement further provided for cross-licensing of all patents covering tetracycline and its preparation by the deschlorination process regardless of which party secured the patent. After an exchange of evidence, Cyanamid conceded priority to Pfizer in February of 1954 and the interference was terminated. At the same time Cyanamid licensed Pfizer to produce Aureomycin for the manufacture of tetracycline.

V

THE SECOND INTERFERENCE

On March 2, 1954, Examiner Lidoff declared an interference on tetracycline hydrochloride between Cyanamid's Minieri application, Bristol's Heinemann application, and Pfizer's Conover application. This declaration constituted a tentative determination that tetracycline hydrochloride was patentable. Several motions were filed by all parties, including a motion by Pfizer to dissolve the interference on the ground that the others did not have a valid claim for tetracycline hydrochloride. Cyanamid moved to dissolve the interference on the ground that tetracycline hydrochloride was not patentably distinct over the disclosures of the Stephens article. During the second interference, numerous briefs and motions were filed that are not particu-

larly pertinent to the issues of this case. In the course of this interference, however, Edelblute denied on at least two occasions that tetracycline was inherently produced in the Duggar or Niedercorn processes. Thus, on June 14, 1954, in conjunction with a motion to add fermentation counts to the interference, Edelblute stated:

> Insofar as the prior art is concerned, none of Duggar, Sobin et al. or Niedercorn show that tetracycline can be produced by fermentation with the use of tetracycline elaborating strains of *Streptomyces*. This result is not inherent and as the discovery represents a major advance in the art, the claims directed thereto are believed to be patentable. (Comm. Ex. 12, p. 36)

In another paper filed with the examiner on August 23, 1954, Edelblute stated: "* * * there is no evidence that tetracycline was inherently produced by the prior art processes of Duggar, Niedercorn, Sobin, or others." (Comm. Ex. 12, p. 383.)

During the second interference Bristol filed various motions to delay the final determination of priority. Bristol commenced selling tetracycline under its own trademark in May 1954, and entered into agreements with Squibb and Upjohn in September 1954, whereby Bristol was to supply Squibb and Upjohn with bulk tetracycline. Both Pfizer and Cyanamid opposed Bristol's efforts to delay the interference proceedings. On July 19, 1954, in opposition to Bristol's motion for postponement of hearing, Edelblute stated:

> It does not appear that any unreasonable hardship or irreparable injury to the party Heinemann et al will result if the motion is denied, but on the contrary, grave injury to the commercial position of the other applicants with respect to the product in issue will occur if this proceeding is delayed by the extension of time requested. It is, therefore, submitted that the motion for postponement should be denied. (Comm. Ex. 12, p. 93)

Pfizer filed an affidavit, signed by Vice President John L. Davenport, stating that Pfizer was losing $50,000 a month in royalties from Cyanamid because of delay in the issuance of the tetracycline patent to Conover. In a subsequent paper filed with respect to Bristol's argument that Cyanamid therefore had no reason for opposing postponement, Cyanamid's counsel responded:

> Cyanamid would rather pay royalties to a bona fide patentee than see the pharmaceutical business in which it has a major interest ruined by irresponsible price cutting. (Comm. Ex. 12, p. 115.)

On October 14, 1954, Lidoff ruled on the various motions filed by the parties. He reversed his former ruling that tetracycline hydrochloride was patentably distinct over the base. This necessitated termination of the interference since it barred Heinemann's claim for the salt, and Minieri was estopped from claiming the salt because its

assignee (Cyanamid) had conceded priority to Pfizer on tetracycline in a previous interference. On his own motion, Lidoff ruled that tetracycline and its hydrochloride were unpatentable as to all parties for an independent reason. The examiner's ruling on this point is set out below:

> The interference count is unpatentable over the disclosures of Duggar U.S. 2,482,055, Sep't 13, 1949 and Niedercorn U.S. 2,609,329, Sep't 2, 1952, and the interference is dissolved. Duggar and Niedercorn each produce an antibiotic, disclosed as "Aureomycin" by a fermentation process employing *Streptomyces aurcofaciens* and mutants thereof. The antibiotic is identified as an antibiotic by assay against bacteria. It appears from the disclosure of Minieri et al. (a party to this interference in an application available to all the parties) that tetracycline is *also* produced in such a fermentation process and that larger proportions thereof are produced when the amount of chloride in the fermentation medium is low * * * Minieri et al. clearly and specifically disclose that the microorganism used to prepare *tetracycline* belongs to the Duggar et al U.S. 2,482,055 species and that "the characteristics are identical with those exhibited by a known culture of *S. aurcofaciens*". While neither Duggar or Niedercorn may have realized that tetracycline was in fact produced, they did appreciate, and disclose, that the product was an antibiotic. No invention is involved in the *identification* of the tetracycline and its hydrochloride inherently produced by the reference processes (see In Re Lieser 1947 C.D. 447; and Allen et al v. Coe 1943 C.D. 55). It has long been held that a purer form of an old product is not inventive and the (apparent) mixture of the prior art meets the count (see Parke-Davis v. Mulford 189 F. 95 and In Re Kebrich 96 US PQ 411). (Emphasis in original.)

The interference was dissolved and on November 24, 1954, the applications were individually rejected (as to their product claims) for the same reason.

The chronological history of the various applications before the Patent Office is outlined in the following chart [pp. 1800–1803 herein]:

VI

THE CONOVER EX PARTE APPLICATION

On October 15, 1954, one day after the disposition of the second interference, Dr. Murphy, a former Pfizer research chemist who was then employed by Pfizer as a patent agent, issued memoranda to two Pfizer scientists, Dr. Fred Tanner and Dr. Virgil Bogert, instructing them to conduct work on the question of coproduction of tetracycline with NRRL–2209, and strain of *S. aureofaciens* which had been deposited by Cyanamid in the public culture collection of the Northern Regional Research Laboratory maintained by the Federal Government. It was made clear to these scientists that the work was in connection with the prosecution of the Conover application and that

the results might be used in preparing affidavits for the Patent Office. Tanner was instructed to summarize all fermentation work that had been conducted to that date with NRRL–2209, "particularly with respect to the proportion of Aureomycin and tetracycline produced in media specifically described or generally disclosed in the Duggar and Niedercorn Aureomycin patents." He was also instructed to conduct fermentation with NRRL–2209 in accordance with the examples set forth in the Duggar and Niedercorn patents and to have each fermentation broth checked for total broad spectrum antibiotic potency. Bogert, in turn, was instructed to recover and purify by the Pidacks Florisil-column method (the method of recovery referred to in the Duggar patent) the antibiotics present in the fermentation broths prepared by Tanner and to determine the total broad spectrum potency. He was also told to determine the Aureomycin and tetracycline content of the recovered products. In connection with the latter instruction, Murphy stated, "This presumably will be determined primarily by paper chromatography tests. However, if other methods are available for determination of this ratio, these should also be utilized." (CX 55, 57, 66)

The Pidacks Florisil-column procedure, a column chromatography procedure disclosed in the Duggar patent as a method of recovering Aureomycin from a fermentation broth, involves a process by which the filtered fermentation liquor is passed through a column filled with a substance to which the antibiotics adhere as the broth passes over it. The column is then "eluted" (washed out) with a proper solvent. As the solvent, containing both antibiotics and impurities, comes out of the column, it is segregated in portions called "bands" or "fractions". Dr. Bogert, in a test run on a Niedercorn broth in November 1954, determined that most of the tetracycline present is destroyed when one strictly follows the Pidacks' procedure, but that the result could be obviated by a slight modification of the procedure. (CX 59, 60; Tr. 4413; CX 58–c)

Paper chromatography is a method that can be used for identifying tetracycline and many other substances. It consists of placing a spot of the material being examined on a strip or sheet of filter paper and allowing a solvent to flow over the paper by capillary action. The paper is removed from the solvent, immobilizing spots of the material which have migrated. Previous tests have established that tetracycline and other products have certain characteristics in the rate at which they migrate. The results of the paper chromotography can be compared against these standards. In the case of an antibiotic such as tetracycline, the spots can be identified by placing

the sheet or strip on a seeded agar plate which will reveal the presence of antibiotic substances. Paper chromatography can be used to determine the percentages of tetracycline present by measuring the zone of inhibition of the bacteria test organism present in the agar medium.

The *Craig countercurrent separation procedure is a method which can be used to separate tetracycline from Aureomycin.* It is based on the manner in which a substance will distribute itself between two immiscible solvents. Two substances which have different distribution coefficients, such as tetracycline and Aureomycin, can be separated by this method.

On October 19, 1954, Werner H. Hutz, Pfizer's outside patent counsel handling the Conover application, wrote a letter to Murphy expressing great interest in the results of the experiments (CX 1027). Notwithstanding this expressed interest, he testified during the hearing that, within two days of this date, he had ordered the work stopped because it occurred to him that he did not know the information the patent examiner would require to overcome the rejection of Pfizer's patent claims. (Tr. 3913). According to Bogert, Dr. Murphy requested him "not to do any more work or make any more entries" in his official notebook. (CX 37, p. 20). The record shows that Bogert continued the tests but recorded the results outside his regular records. (CX 58)

Pursuant to the original instructions given by Murphy, Dr. Tanner prepared several broths, among which were two broths prepared in accordance with the specifications set forth in Niedercorn Example I. One of these broths had a bio-assay potency of 75 micrograms per milliliter (calculated as Aureomycin). Bogert applied a modified Pidacks procedure to this broth and obtained a number of fractions which were found by paper chromatography to contain tetracyline. Bogert testified that these tests showed tetracycline to be present and to be present in quantities "not more than five per cent." (Tr. 4412) Bogert did not attempt to isolate the tetracycline. The Commission has found on the basis of expert testimony that tetracycline could have been recovered from these fractions as of October 1954 by the Craig countercurrent separation procedure. (Tr. 2826, Tr. 11,032; 11,043–11,045)

On November 29, 1954, Hutz and Murphy conferred with the patent examiner. In accordance with Patent Office practice, a summary of what transpired at this conference was drafted and filed by Hutz at the next conference on December 8, 1954. This sum-

mary [5] shows that Hutz and Murphy argued to the examiner that there was no reasonable basis for his speculation as to coproduction of tetracycline in the prior art processes and that "The available evidence is overwhelmingly contrary to the Examiner's assumption." The patent examiner informed Pfizer's representatives that he would withdraw his rejection of Pfizer's tetracycline product claims if Pfizer could demonstrate that tetracycline could not be recovered in clearly identifiable form from fermentation broths produced strictly in accordance with the Duggar and Niedercorn disclosures, using the strain *S. aureofaciens* NRRL–2209 which had been deposited by Cyanamid with the Northern Regional Research Laboratory as part of its disclosure requirements in receiving the Duggar patent.

The Niedercorn patent contained a large number of examples of media, however, and Pfizer used Example 28. Hutz testified that the examiner selected this example himself and required Pfizer to use it because it appeared to contain only a trace of chloride ion. It is evident, however, that the examiner was interested in the possible production of tetracycline in any of the Niedercorn examples. The Pfizer representatives did not disclose that Bogert had previously found that NRRL–2209 fermented in the medium described in Example I of the Niedercorn, produced a broth of 70 micrograms per milliliter, and that using a modified Pidacks method and paper chromatography he had found approximately 5 per cent of the filtered broth to consist of tetracycline.

Furthermore, in September of 1954, two months earlier, Tanner, as part of a general research project to determine the production of tetracycline by various means of fermentation, had fermented NRRL–2209 in a Niedercorn 28 medium and had found the resulting broths to be less than 10 micrograms per milliliter. *These broths were so poor in antibiotic potency that they were classified as containing no Aureomycin or tetracycline.* These findings, which were relevant to the patent examiner's determination of which examples in Niedercorn to use, were not disclosed to him. When Tanner prepared the affidavit-test broths, the Niedercorn Example 28 had approximately the same low level of potency as the similar broths prepared by Tanner in September.

After the oral interview of November 29, 1954, Murphy immediately notified Tanner and Bogert that tests were to be conducted for the Patent Office to determine whether tetracycline could be recovered

[5] The summary is set forth in the Findings at p. 1773.

from Duggar and Niedercorn Example 28 broths using the three recovery procedures described in the Bogert-Walsh, Minieri, and Heinemann applications. Tanner prepared two broths—one as representative of the example set forth in the Duggar specifications and one as representative of the Niedercorn Example 28 broth. These broths were respectively designated as broths 1771A & 1771B. When these broths were turned over to Bogert, both biological and chemical assays were made by other Pfizer technicians at the request of Bogert. The potency of 1771B was assayed at 5.2 micrograms per milliliter (as Aureomycin) (14.3 by chemical assay). The record establishes that for low potency broths, the biological assays are more accurate. These potency figures were unusually low in comparison to the potencies set forth in the Niedercorn patent. (No potency figures were disclosed in Duggar.) Although Niedercorn did not specify the microorganism used, Example 28 discloses that a broth potency of 274 micrograms of Aureomycin per milliliter was obtained. Other examples set forth in Niedercorn show potencies ranging from approximately 100 to 400 micrograms per milliliter.

Notwithstanding the low potencies of the test broths, the papers filed by Pfizer with the examiner indicated that these broths were "representative" of the Duggar and Niedercorn broths. The potency figures were not set forth or otherwise indicated. Expert testimony establishes that there is no way that Lidoff could have calculated the potencies of the test broths from the data contained in the affidavits. (Tr. 1912, 2869) The record also clearly establishes that the low potencies of the broths were a crucial factor in Pfizer's failure to recover tetracycline. (Tr. 1983–84, 4439) Under these circumstances, the statement that the broths were "representative" of the Duggar and Niedercorn broths was clearly misleading.

In this connection, the affidavit prepared by Tanner omitted a fact that may have been material to the patent examiner's determination of whether Niedercorn Example 28 was sufficiently duplicated. In his affidavit, Tanner indicated that the entire forty-hour fermentation (tank fermentation) was conducted in a medium having a pH value of 6.7. The Niedercorn patent states that for maximum growth it is necessary that the pH of the fermentation medium be controlled within rather narrow limits and that "Highly effective growths may be obtained within the range of about 5.0 to 8.0. Best results are obtained within the range of approximately 6.4 to 7."

In fact, Tanner's laboratory notes (CX 61) show that the medium was initially adjusted to 6.8 (which was recorded in the affidavit as 6.7), but after sterilizing the medium preparatory to inoculation, he

found the pH to be 8.1. Without further adjustment of the pH, Tanner inoculated the medium and began the fermentation with the pH at 8.1. Six and one-half hours later Tanner returned to the laboratory and found the pH still tested at 8.1. Tanner then adjusted the medium with sulphuric acid to bring down the pH value. During this six and one-half hour period, it was observed that no growth of the organism occurred. These facts were not disclosed to the patent examiner. Instead, the affidavit clearly conveys the false impression that the pH was constantly kept within the optimum range.

The two test broths prepared by Tanner were turned over to Bogert for recovery work. As noted before, Bogert had these broths assayed by both biological assay and chemical assay methods. Although the assays showed the broths to have little antibiotic content, Bogert proceeded to apply three commercial recovery procedures which were designed for direct recovery of tetracycline from higher potency broths. For example, one procedure was to be applied to a broth containing at least 100 micrograms per milliliter of tetracycline. The test broths used by Bogert, however, had only 5 to 7 micrograms of tetracycline and Aureomycin combined. Nevertheless, Murphy and Hutz represented that the techniques used were the best procedures designed for recovering any tetracycline present in the test broths.

In fact, other procedures were available which were more suitable for recovering tetracycline from low potency broths where the percentage of tetracycline approximates 5 to 10 percent of the antibiotic material. These procedures were the column chromatography method and the Craig countercurrent distribution method. The latter method could have been used in conjunction with column chromatography or with the Bogert-Walsh recovery method. (Tr. 11,031–033, 11,042, 11052)

The record shows that Murphy and Hutz knew that the examiner was under the impression that the Pidacks Florisil-column chromatography method was suitable only for obtaining *Aureomycin* fractions from fermentation broths. Before representing to the examiner that the procedures used were the best available, they were under a duty to ascertain from Pfizer scientists what procedures were available. The record shows that earlier in November Bogert had successfully applied a modified Pidacks method to broths containing tetracycline. The record shows that Murphy instructed Bogert to use only the three procedures described in the Bogert-Walsh, Minieri, and Heinemann applications. (Tr. 4273)

Bogert's affidavit describes in detail the recovery techniques he applied. A few amorphous products were recovered, all having a low antibiotic content. As to the amorphous product obtained by the

procedure taken from the Bogert-Walsh patent application, Bogert stated:

> This product was tested in a manner that he knows is capable of detecting even a small proportion of tetracycline in the presence of chlortetracycline and showed only chlortetracycline.

The Tanner-Bogert affidavits were submitted by Hutz and Murphy to the examiner on December 8, 1954, together with their own "Remarks" summarizing their version of the November 29 conference and an amendment of seven new claims. After examining these papers, the examiner requested more information as to the possibility of recovering tetracycline. The next day, December 9, Hutz and Murphy conferred again with the examiner. They submitted a supplemental affidavit signed by Bogert. Bogert's supplemental affidavit recited that he had applied an acid color test which should show whether the amorphous product recovered from broth 1771A by Procedure A contained 20 percent or more tetracycline. He concluded:

> Based on these results and on his experience with the results of a great many such tests on materials containing tetracycline, chlortetracycline and mixtures thereof, he is convinced that not nearly as much as 20% of the potency of the amorphous material could be due to the presence of tetracycline, in fact there was no indication whatever of the presence of tetracycline. Assuming that the maximum possible proportion of the total potency due to tetracycline is 10%, this means that the 0.36 grams of amorphous material cannot contain more than about 0.009 grams of tetracycline. He does not know of any method whereby any part of such a minute amount of tetracycline could be separated and recovered in clearly identifiable form from the amorphous material.

Bogert's affidavit further stated that in each instance in which amorphous material had been recovered, the amount was so small and the potency so low that he knew of no method whereby "any part of the minute amount of tetracycline conceivably present could be separated and recovered in a clearly identifiable form." On the assurances given in the aforementioned affidavits and remarks, the patent examiner on December 9, 1954, granted a notice of allowance to Pfizer and the tetracycline patent was issued to Pfizer on January 11, 1955.

Several months later, in May of 1955, Edelblute filed papers in Cyanamid's Minieri application in which he stated that recent investigations were made by Cyanamid of the Duggar fermentation using various strains of *S. aureofaciens* and it was found that under certain conditions and when using some strains of *S. aureofaciens* small amounts of tetracycline had been produced. He also stated that "reinvestigation" of samples of commercial Aureomycin showed from 1 to 2½ percent tetracycline. (CX 8, p. 81)

During the same month, however, in a Pfizer application for a

process of recovering tetracycline from a fermentation broth, Hutz, Pfizer's patent attorney, stated that tetracycline had not existed in Duggar fermentations as an impurity and that "*It is believed that the Patent Office is now aware that this 'inherent' production is not in fact true.* Tetracycline would most emphatically not be an 'impurity' in the prior art method as the Examiner believed at the time of his last office action herein, and applicants' process would not be inherently performed by the reference." (CX 13, p. 16.) (Emphasis Added.)

The Heinemann applications were eventually abandoned by Bristol whose attorneys took the position that tetracycline was unpatentable because Bristol tests showed that tetracycline had been coproduced with Aureomycin.

On the same day that Pfizer received a patent on tetracycline, it brought infringement suits against Bristol, Squibb and Upjohn, seeking damages and a restraining order preventing them from marketing tetracycline. (Squibb and Upjohn had been buying tetracycline from Bristol in bulk and selling it in dosage form to the drug trade for several months.) Bristol, Squibb and Upjohn brought actions in the Southern District of New York seeking declaratory judgments that they were not infringing any valid claim of Pfizer's patent. In their answers to the Pfizer complaint they claimed the Conover patent was invalid because, among other things, it had been allowed by the Patent Office under a mistake of fact induced by Pfizer and that the claims of the patent were unenforceable because of Pfizer's "unclean hands" arising from its misrepresentations of fact to the Patent Office in its prosecution of the application on which the patent was obtained. Throughout most of 1955, Bristol, Squibb and Upjohn took numerous depositions of Pfizer's officials and technical workers and subpoenaed documents from Pfizer. These depositions were introduced as evidence in this proceeding by complaint counsel and support the defenses referred to above. The suits were eventually settled with Bristol receiving a license to manufacture *and* sell tetracycline. Squibb and Upjohn received licenses to sell tetracycline to the drug trade. The licensees were required to pay Pfizer a royalty of 3½ percent of net sales.

VII

ALLEGED MISREPRESENTATIONS AND WITHHOLDING OF INFORMATION BEFORE THE PATENT OFFICE

The hearing examiner dismissed the above charge for the reason that any misstatements of fact or withholding that the record discloses pertains to matter which was immaterial to the Patent Office's

determination of the validity of Conover's product claims.[6] We disagree. *We find that the hearing examiner's decision is based on a misunderstanding of the patent examiner's rulings on tetracycline.* The hearing examiner's entire decision on this phase of the case contains a series of deductions from certain erroneous assumptions. He assumes (erroneously) that the Patent Office examiner, Lidoff, dissolved the second interference and rejected the Conover (Pfizer) product claims on the speculation that tetracycline, as an inherent part of commercial Aureomycin products, had been in *public use or on sale* more than one year before the date of Conover's application.[7] From this, and from certain conclusions of law based on decisions that Lidoff never relied upon, he reasons that Lidoff must have been interested only in whether tetracycline was present in the final commercial product of Aureomycin and whether it was present in "substantial quantities" so as to impart utility to that product. From this he reasons that Lidoff's motive in requiring Pfizer to run tests was to determine whether tetracycline was present in the broth in (again) "substantial quantities" so that such quantities could have been recovered along with Aureomycin. From this conclusion and from erroneous findings that Lidoff always knew of coproduction of tetracycline in smaller amounts (less than "substantial") in the prior art processes and that Pfizer "conceded" that tetracycline constituted ten percent of Aureomycin, he reasons that no *material* misrepresentations or withholding of information occurred because the evidence shows that tetracycline almost always constituted something less than ten percent of Aureomycin.

The Commission contrary to the above conclusions by the hearing examiner, finds that:

(1) The patent examiner did not reject Conover's product claims on the ground that tetracycline may have been in public use or on sale more than one year before the date of Conover's application, but rather his rejection was based on the ground that it appeared that tetracycline was inherently produced by the fermentation processes

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[6] During the trial of this case, counsel supporting the complaint attempted to show that Pfizer made false statements and withheld information as to (1) coproduction of tetracycline in Aureomycin fermentation processes, and (2) the state or knowledge of the structure of Aureomycin and Terramycin at the time of Conover's discovery of tetracycline. The hearing examiner found against counsel supporting the complaint on both charges. Counsel supporting the complaint have taken exception to his findings as to the first charge. Consequently, our review of the patent phase of this case will be confined to the first charge.

[7] The Patent Office, in accordance with its general policy of not allowing its examiners to testify as to applications they have reviewed, did not allow Lidoff to testify in this case.

described in the Duggar and Niedercorn patents and for the reason of inherent production alone would be unpatentable.

(2) Nowhere in the documents before the patent office did respondents or the patent examiner even allude to the public use and sale theory.

(3) The patent examiner informed Pfizer that he would not allow tetracycline product claims unless Pfizer submitted affidavits in which Pfizer scientists swore they could not recover tetracycline from broths representative of those described in the Duggar and Niedercorn patents.

(4) Pfizer submitted such affidavits and the examiner allowed the claims, thereby enabling Pfizer to obtain a patent on the product tetracycline.

(5) Pfizer deliberately made false and misleading statements regarding the affidavit tests and suppressed the fact that Pfizer had previously found that tetracycline was produced by one of these fermentation processes.

(6) The patent examiner did not previously know that inherent production occurred in any of these processes and was not told of this fact by Pfizer, nor did Pfizer concede that tetracycline constituted ten percent of Aureomycin (or any other percentage, for that matter).

(7) The false statements and information withheld were material to the patent examiner's determination of the patentability of tetracycline and were known by Pfizer to be material.

To come to any other conclusion would be to torture the English language and make semantics rather than facts the basis for our rulings.

Public Use and Sale: The theory of law that the hearing examiner imputes to the mind of the Patent Office examiner Lidoff is based on the assumption that Lidoff dissolved the second interference and rejected the Conover claims on the ground that tetracycline had been in *public use or sale.* After he cites 35 U.S.C. Sec. 102 of the Patent Code which includes in paragraph (b) the statutory bar against a patent for an invention that has been in public use or sale in the United States more than one year prior to the date of application, the hearing examiner reviews numerous decisions and states at page 108 of his decision:

> The cases clearly establish that the prior unknown existence of a product, subsequently discovered, in another product which has been in public sale or use, does not constitute a disclosure barring patentability within the meaning of the statute. The exception to this principle relied upon by Lidoff, hereinabove

discussed * * * was when the product, although unknown, had been on sale as part of, and imparted the utility to, a known product. The discovery and isolation of such a new product possessing the same utility is not patentable because no benefit is conferred upon the public, which as a result of the public sale had the utility available even though the source of the utility was not known or disclosed.

The hearing examiner's characterization of the statutory grounds upon which Lidoff rejected the Conover product claims is unsupported by an evidence of record. The record clearly indicates that Lidoff, rather than basing his rejection on the ground that tetracycline may have imparted utility to a product in use or on sale, speculated that Conover had discovered a product which had already existed in a prior art fermentation process that was described in prior patents as producing an "antibiotic substance" and for this reason lacked novelty that could not be patented. Although Conover was the first to identify tetracycline and its chemical structure, Lidoff ruled that *identification* of a substance that was inherently produced by a known process did not constitute a patentable invention. The reference by Lidoff to the Duggar and Niedercorn patents was reference to prior art that corresponds to Section 102(e): "A person shall be entitled to a patent unless—(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent." See also 35 U.S.C. Sec. 102(f). To clarify this matter and show that the hearing examiner's conclusion is erroneous, it will be necessary to review the theoretical foundations of patent law, in particular the concept of "prior art," and the practice of Patent Office examiners' references to prior art.

There are three basic requirements for a patent: invention, novelty, and utility. *Cuno Engineering Corporation* v. *Automatic Devices Corporation*, 314 U.S. 84, 90 (1941).[8]

Invention: The concept of invention is not defined by statute other than the statement in Section 100[9] that it is an "invention or discovery" and the provision in Section 103 (enacted in 1952) that a patent may not be obtained if the differences between the subject matter and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Nearly all courts construing this provision have held that

[8] The requirement of utility is not reviewed herein as there is no issue as to the usefulness of tetracycline. The hearing examiner's referral to the concept of "new and different utility" relates to the question of novelty.

[9] Statutory references are to sections of Title 35 of the United States Code.

it does not change the standard for invention as applied by courts prior to its enactment in 1952.[10]

This standard cannot be readily summarized as it is composed of various negative definitions of invention as applied to particular factual situations.

Novelty: After Section 101 states that an "invention" can be patented, it adds the phrase: "* * * subject to the conditions and requirements of this title." The next section includes the requirements concerning novelty (and loss of patent rights).

35 U.S.C. 102. Conditions for patentability; novelty and loss of right to patent. A person shall be entitled to a patent unless—

(a) The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country or an application filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

A careful reading of Sections 102(a) and 102(b) will show that the difference between them lies in the priority of invention and timely filing of an application. Section 102(b) applies to situations

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[10] See, *e.g., In re Krogman,* 223 F. 2d 497 (C.C.P.A. 1955); *Wasserman* v. *Burgess and Blacher Co.,* 217 F. 2d 402 (1st Cir. 1954); *Stanley Works* v. *Rockwell Mfg. Co.,* 203 F. 2d 846 (3rd Cir. 1953), *cert. denied* 346 U.S. 818 (1953); *General Motors Corp.* v. *Estate Stove Co.,* 203 F. 2d 912 (6th Cir. 1953), *cert. denied* 346 U.S. 822 (1953); *Helms Products* v. *Lake Shore Mfg. Co.,* 227 F. 2d 677 (7th Cir., 1955); *Caldwell* v. *Kirk Mfg. Co.,* 269 F. 2d 506 (8th Cir. 1959) *cert. denied* 361 U.S. 915 (1959).

Section 103 also contains a provision that "Patentability shall not be negatived by the manner in which invention was made." A remark in the *Cuno* case, *supra,* characterizing invention as a "flash of creative genius" had been interpreted by some courts as a new standard for invention. The Reviser's note to Section 103 indicates that this provision was intended to overcome any such inference. *Cf. Lyon* v. *Bausch & Lomb Optical Co.,* 224 F. 2d 530, 537 (2nd Cir., 1955).

where not only another person's invention has been patented, described, or publicly used, or on sale more than one year prior to the date of application, but where the applicant's invention has been so used or sold.[11] Both these paragraphs and paragraph (e) overlap each other to some extent in the situations they cover. All paragraphs except (c), (d), and (f) would usually overlap the independent requirement that "invention" be established; that is, a failure to meet the standard for novelty under Section 102 because of prior public knowledge,[12] use by others in this country, prior patent, or description in a patent or printed publication, public use or sale in this country, would in nearly all instances fail to meet the more rigorous standard for invention over the prior art.[13]

"Prior art" is a term which covers the state of public knowledge in a particular science or skill. Those references to patents and printed publications which are considered applicable for purposes of determining whether a discovery is novel and inventive constitute what is known in patent law as references to the prior art. A patent examiner, when rejecting a claim by citing prior art, does not usually need to cite the statutory ground for his rejection since in most instances the basis for the rejection is apparent from the language employed.[14] Patent Office examiners would rarely have occasion, it would seem, to reject an application on the ground of prior public use or sale, as their time is spent in searching the technical literature of the prior art.[15]

The Patent Examiner's Rejection Was Based on Section 102 (e)

Section 102(e) creates a statutory bar when the applicant's claim was anticipated by a description in another party's patent, the application date of which was prior to the applicant's date of invention. The predecessor of this section was interpreted by the Supreme Court

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[11] The policy behind this provision is to encourage prompt filing and discourage attempts to extend the statutory monopoly. *Shaw* v. *Cooper,* 32 U.S. (7 Pet.) 292, 320 (1833).

[12] The requirement that the knowledge be "public" knowledge was added by judicial construction in *Pennock* v. *Dialogue,* 27 U.S. (2 Pet.) 1, 18–19 (1829).

[13] Pfizer's product claims in the Conover application presented an instance where the applicant's discovery was not obvious to one skilled in the art and yet was not patentable if coproduction occurred since this would negate novelty. Lidoff asserted that if tetracycline existed in the prior art it could not be patented. An analogous situation is where the substance previously existed in nature. See *e.g., In re King,* 107 F. 2d 618 (C.C.P.A. 1939).

[14] Patent Office Manual of Patent Examining Procedure, 3rd ed., Sec. 707.07(d).

[15] *Id.* Sec. 901.06(a). Section 706.03(v) of the Manual of Patent Examining Procedure expressly provides for the rejection of claims on the ground of prior use or sale where "public use proceedings" have been instituted and have terminated with the finding that prior use or sale was established. Public use proceedings are special hearings instituted at the direction of the Commissioner. Patent Office Rule 292.

in *Alexander Milburn Co.* v. *Davis-Bournonville Co.*, 270 U.S. 390 (1926), to mean that the disclosures in the specifications of the patent can anticipate the applicant's claim even though the prior patent did not *claim* the anticipatory art disclosed therein.[16] Anticipation results even though the prior patentee may not have appreciated the significance of the disclosure.[17] An applicant may show the prior art patent to be inapplicable, if he can, by submitting affidavit and proof under Rule 132 of the Patent Office Rules.

Against this background of patent law and Patent Office procedure it becomes evident that Lidoff did not dissolve the second interference and reject the Conover product claims on the ground of prior public use and sale one year before the application. Lidoff's stated ground for finding tetracycline unpatentable was:

> The product claims are unpatentable over the disclosures of Duggar, U.S. 2,482,055, Sept. 13, 1949 and Niedercorn, U.S. 2,609,329, Sept. 2, 1952. Duggar and Niedercorn each produce an antibiotic, disclosed as "Aureomycin" by a fermentation process * * *. It appears from the disclosure of Minieri, et al. (a party to Interference No. 86, 861) in an application available to all parties that tetracycline is also produced in such a fermentation process * * *. While neither Duggar and Niedercorn may have realized that tetracycline was in fact produced, they did appreciate, and disclose that the product was an antibiotic. No invention is involved in the *identification* of the tetracycline and its hydrochloride inherently produced by the reference processes (see In re Lieser, 1947 C.D. 447 and Allen et al v. Coe, 1943, C.D. 55). It has long been held that a purer form of an old product is not inventive and the (apparent) mixture of the prior art meets the claims (see Parke, Davis v. Mulford, 189, F. 95 and In re Kebrich, 96 USPQ 411). (Emphasis in the original) (CX 12, pp. 443–4; CX 4, pp. 31–32)

There is no indication in the above rejection of any speculation that tetracycline would be unpatentable for the reason that it was in public use or sale more than one year before the date of application. Nevertheless, the hearing examiner reasons at page 47:

> The presence of tetracycline in the fermentation broths was not a prior public sale or use, since such broths were never in public use or sale. However, if the resultant product Aureomycin, having been sold since 1948, contained tetracycline, it could be argued that tetracycline had been in public use and sale. * * *
>
> In his rejection and rulings on the second interference the examiner specifically referred to the disclosure of Minieri that tetracycline was also produced in the fermentation process and that larger proportions were produced under certain conditions. He pointed out that, while Duggar and Niedercorn did not realize that tetracycline was in fact produced, they did appreciate and

[16] Section 102(e) is the statutory enactment of the *Milburn* decision. See Reviser's Note to Section 102.

[17] *In re Lieser*, 162 F. 2d 224 (C.C.P.A. 1947); *Allen* v. *Coe*, 135 F. 2d 11 (D.C. Cir., 1943); *In re Gauerke*, 86 F. 2d 330 (C.C.P.A. 1936).

disclose that the product was an antibiotic. It will be noted that he made specific reference to the product at this point. Counsel supporting the complaint failed to distinguish between inherent production in the broths and in the product, and contend that inherent production in the broth would constitute a bar to patentability. For the reasons pointed out above, this clearly is not correct.[18]

On the contrary, there is no indication whatsoever that Lidoff was concerned with commercial Aureomycin products. The record clearly shows that Lidoff's rejection was based on the theory that the description in prior art patents of a process which is disclosed as producing antibiotic substance, part of which is tetracycline, constitutes an anticipation of any later product claims for tetracycline. Lidoff's reference to a "product" in the sentence "While neither Duggar or Niedercorn may have realized that tetracycline was in fact produced, they did appreciate and disclose, that the product was an antibiotic" was obviously a reference to the antibiotic substance (called Aureomycin) produced by the fermentation process which Lidoff speculated was actually a mixture of tetracycline and chlortetracycline. This was not a reference to the final commercial Aureomycin *products* as the hearing examiner surmised.

The hearing examiner does not even consider the possible relevance of Section 102(e) to Lidoff's rejection and merely assumes it was based on prior use and sale. Indeed, it appears that not even counsel for respondents argued that this was the basis for the rejection. Pfizer has contended throughout that Lidoff knew that the microorganism he required Pfizer scientists to use for the affidavit tests was a microorganism that was unsuitable for commercial production of Aureomycin. Therefore, the "public use and sale" theory lacks support even under respondent Pfizer's interpretation of Lidoff's rulings.

The Hearing Examiner's View of the Law

As seen from the foregoing, the hearing examiner erroneously finds that Lidoff was interested only in whether tetracycline was present in commercial Aureomycin products. From this and from certain conclusions of law, discussed in the following pages, the hearing examiner reasons that Lidoff must necessarily have been interested only in whether tetracycline was present in commercial products in "substantial quantities" so as to impart utility to the commercial product.[19]

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[18] In support of the above conclusion, the hearing examiner states that Lidoff already knew that tetracycline was coproduced in the prior art broths. This finding is erroneous and will be discussed later in this opinion.

[19] At page 57 of his decision, the hearing examiner appears to define "substantial quantities" as meaning quantities constituting fifty percent or more of the products.

Although recognizing that the issue of misrepresentation to the Patent Office was a basic issue in this case, the hearing examiner himself ruled on the question of ultimate patentability of tetracycline. Thus, at page 82, he states:

> Because certain allegations depend upon the legal significance of inherent production on patentability, it becomes material to determine whether or not the coproduction demonstrated in the record constituted such prior knowledge or use, public sale or use, or the other statutory bars, as to render the discovery of tetracycline unpatentable * * * In short, with respect to inherent production, it becomes necessary to ascertain, first, what the Patent Office wanted to know about coproduction, and what was represented to and/or withheld from it with respect thereto, and, second, independently of any such representations or withholdings, whether or not the facts concerning coproduction establish lack of patentability.

Although some of the allegations in the complaint do allege nonpatentability of tetracycline, other allegations charge simply that the Conover patent was issued as a result of misrepresentations submitted to the Patent Office. As we shall discuss in another portion of this opinion, *the enforcement of a patent whose acquisition was attended by substantial false representations constitutes an unfair method of competition within the meaning of Section 5 of the Federal Trade Commission Act*, and it is not necessary that we make an independent determination as to the patentability of tetracycline, although in the course of our opinion it will be necessary to discuss the legal theory adopted by the patent examiner who reviewed the Conover application. Whether tetracycline is or is not patentable is a question of law upon which opinions could differ. We hold the hearing examiner clearly erred in his findings regarding Lidoff's motive for having Pfizer run fermentation tests. It is evident from the hearing examiner's decision that he failed to keep distinct the difference between a question of fact and a question of law.

The hearing examiner, instead of first determining by the record the question of *fact*—what did the patent examiner, Lidoff, consider to be an anticipation of the Conover claim for "tetracycline"—examines various patent law decisions to determine whether tetracycline is patentable. He concludes that there is good authority for the argument that a court, having all the facts concerning the coproduction of tetracycline in the Duggar and Niedercorn processes, should, nevertheless, rule that tetracycline is patentable. The hearing examiner cites and discusses at length various decisions (that were not relied upon by Lidoff) in support of his conclusion as to patentability of tetracycline. Those cases which Lidoff did cite [20] in rejecting tetra-

[20] *In re Lieser*, 162 F. 2d 224 (C.C.P.A. 1947); *Allen* v. *Coe*, 135 F. 2d 11 (D.C. Cir., 1943); *Parke-Davis & Company*, v. *H. K. Mulford Co.*, 189 Fed. 95 (C.C.S.D.N.Y. 1911), *aff'd* 196 Fed. 496 (2d Cir., 1912); and *In re Kebrich*, 201 F. 2d 951 (C.C.P.A. 1953).

cycline claims and in dissolving the second interference are not fully discussed by the hearing examiner, and are distinguished on the ground that they were cases involving process claims rather than product claims (a "distinction" which was meaningless for the purpose for which Lidoff cited them), and finally are dismissed as not being the "best examples" of what Lidoff could have cited. The hearing examiner in discussing the cases he considered more "in point" and coming to the conclusion that tetracycline is a patentable invention, states at page 85 of his decision:

It must be assumed, of course, and the record establishes, that Mr. Lidoff was completely familiar with the patent laws and decisions and applied the appropriate precedents to his reasoning and rulings.[21]

Thus, the hearing examiner conceives that there is one definite law as to anticipation by prior inherent production and that Lidoff must have applied it. The hearing examiner's conclusion as to the "true" law of inherent production is stated at page 90:

In summary, if a product has been inherently produced in an old product, but this was unknown, undisclosed, and imparted no utility to the prior product, such inherent production does not bar patentability.

After only a brief discussion of three of the four cases that Lidoff cited in support of his rejection, the hearing examiner, as noted, dismisses them as not the best examples that Lidoff could have cited. In discussing the fourth case, *Parke-Davis* v. *Mulford*,[22] the hearing examiner fails to comprehend Lidoff's reason in citing that case.

The hearing examiner states at page 86 of his decision:

Contrary to the contentions of counsel supporting the complaint, there are no cases which stand for the proposition that a newly discovered product, which had existed unknown and undisclosed as part of a prior compound and which possesses a different utility from the prior compound, is not patentable.

This may be true, but it is clear that Lidoff did not consider that tetracycline in mixture and tetracycline isolated have different kinds of utility. Tetracycline in both forms is an antibiotic. Lidoff made this clear in his rejection, stating at one point:

While neither Duggar and Neidercorn may have realized that tetracycline was in fact produced, they did appreciate and disclose that the product was an antibiotic.

[21] Two of the cases which the hearing examiner discusses at great length to prove his point, one of which he says goes even further in finding patentability than would be required in the case of tetracycline, are 1958 decisions. Lidoff in rejecting the Conover claims in 1954 could not have been familiar with these decisions even assuming they would now serve as precedents if tetracycline patentability was an issue. Furthermore, the record shows that the other decisions that are similar in their facts are decisions of which Lidoff was aware. They had been cited to him and discussed at length by Bristol several times during the second interference in connection with other issues. Lidoff obviously did not consider them controlling as to tetracycline.

[22] *Parke-Davis & Co.* v. *H. K. Mulford Co.*, 189 Fed. 95 (C.C.S.D.N.Y. 1911), *aff'd* 196 Fed. 496 (2d Cir. 1912).

Lidoff's remarks then make it clear that he did not consider a purer form of tetracycline to be of a different kind of utility. He stated:

It has long been held that the purer form of an old product is not inventive and the (apparent) mixture of the prior art meets the claim (see Parke, Davis v. Mulford * * * and In re Kebrich * * *).

The *Parke-Davis* case, decided in 1911 by Judge Learned Hand, announced the general rule that a purer form of an old product is not inventive, but found an exception to that rule in the case where extraction and purification created a product which has a new utility that is different in kind rather than merely different in degree. The hearing examiner assumes that Lidoff cited *Parke-Davis* for the exception rather than for the general rule. But it is apparent to us from Lidoff's language and from the fact that the case was cited in *rejecting* Conover's claims that this case was cited for the general rule therein. If Lidoff had cited the case for the exception to the rule, then the citation would make sense only if he were allowing Conover's claims.

Moreover, it is clear to us that *Parke-Davis* was cited for another, but related, rule of law—that a claim for "tetracycline" (a broad claim) would be anticipated by the existence of tetracycline in any form in the prior art, even if it previously existed in mixture with another antibiotic substance. *Parke-Davis*, although noted for the general rule and exception referred to above, also recognized the principle that a broad claim which covers not only the pure form of a product, but the product in any environment, is anticipated by the prior existence of the product in mixture form (189 Fed. at 102).[23] Lidoff's citation of the case for this latter principle is evidenced by his statement that "the (apparent) mixture of the prior art meets the claims." It is further evidenced by the fact that in rejecting the Heinemann application on December 8, 1953, Lidoff cited *Parke-Davis* for that proposition alone.[24]

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[23] See S. H. Philbin's discussion of this aspect of *Parke-Davis* in *Judge Learned Hand and the Law of Patents and Copyrights*, 60 Harv. L. Rev. 394, 398 (1947).

[24] "Product claims 1 to 7, 18 to 20 are similarly rejected as being unpatentable over each of Duggar and Niedercorn since it appears, from the processes thereof, that applicant's product must be produced inherently. *The claims read on the product in any environment.* (See In re Kebrich 671 O.G. 597 and Parke, Davis v. Mulford, 189 F. 95.)" (CX 9, p. 31. Emphasis added.)

It should also be noted that *Parke-Davis* did not involve the question of "imparting utility". The facts of that case were that the pre-existing impure ingredient did impart its utility to a mixture (dried glands). The court found a difference in kind (rather than degree) to exist between the old mixture and the extracted ingredient because the dried glands contained other substances (organic tissue matter) which gave them dangerously toxic qualities. Lidoff was fully aware that Aureomycin products were therapeutically useful and not dangerously toxic as were the dried glands in the *Parke-Davis* case.

Apparently in support of the theory that pure tetracycline would have a different utility from Aureomycin, the hearing examiner states: "In fact, the record establishes that tetracycline was an impurity in the prior art product and rather than contributing to its utility detracted from it." This is not supported by the record and is contrary to what the evidence shows. But an impurity does not necessarily detract from utility. Both substances serve the same antibiotic purpose. To remove one is simply to obtain a purer but no more effective form of the other. Moreover, nothing indicated that tetracycline would limit Aureomycin's utility.

Process v. Product Claim Rejections

In support of his conclusion that Lidoff was interested only in knowing whether substantial quantities of tetracycline were coproduced, the hearing examiner theorizes that Lidoff applied different standards for product and process claims—that any amount of prior production would anticipate a process claim, but that only the production of "substantial" amounts would anticipate a product claim.[25] There is no indication that Lidoff so regarded the law. It appears that the source of this distinction lies in the fact that the hearing examiner, in imputing the "public use and sale" theory to Lidoff, could not otherwise account for process claim rejections.

In support of his theory that Lidoff required a greater quantum of inherent production of tetracycline to anticipate a product claim than to anticipate a process claim, the hearing examiner cites instances where Lidoff rejected process claims but not product claims on that basis. It is true that on October 29, 1953, Lidoff rejected the *product claims* in Heyden's Minieri application on the ground of anticipation by the Stephens' article and the *process claims on the ground of prior inherent production.*[26] Lidoff at this time sent notices to copy claims to Pfizer and Cyanamid indicating that an interference on the product tetracycline would be declared. He informed Minieri's attorney at the same time that if Minieri submitted an affidavit under Rule 131 swearing back of the Stephens' article that Minieri would then be eligible as a party to an interference on "tetracycline." Lidoff would not have rejected Minieri's product claims at the same time on the basis of inherent production since that would have barred Minieri from the proposed interference. (Lidoff had reason to have the question of priority among the three parties determined, as his theory of prior inherent production in the Duggar and Niedercorn

[25] Initial Decision, pp. 19–20, 29, 44–45.

[26] See p. 1812 *supra* in this opinion.

processes was merely speculative and might later prove to be incorrect.) As it happened, Minieri did not enter the interference on the count for tetracycline as Cyanamid bought Minieri's rights from Heyden and elected to rely on the Boothe-Morton application in the first interference. *In the next ex parte office action in rejecting the Minieri claims, Lidoff was able to, and in fact did, reject Minieri product claims on the ground of prior inherent production.*

Lidoff first asserted the doctrine of inherent production against a product claim on December 8, 1953, in Bristol's Heinemann application. Lidoff at this time did not anticipate that Heinemann would be a party to any interference involving tetracycline as Heinemann was barred by the fact that the Stephens' article was published more than a year before the date of Heinemann's application. Therefore, there was nothing to prevent Lidoff from rejecting both process and product claims of Heinemann on the ground of prior inherent production and the product claim also on the basis of the Stephens article.[27]

As to the Martin-Bohonos (Cyanamid) rejection of process claims on the ground of inherent production on December 11, 1953, it is clear that Lidoff would not reject the product claim therein on the basis of prior inherent production, since that would have been inconsistent with his previous notice to the common assignee Cyanamid to copy claims in the Boothe-Morton application on a proposed interference count on the product "tetracycline". As noted above, Lidoff, at this time, was favorable to having the question of priority settled in the first interference since his theory of inherent production in Duggar and Niedercorn was merely speculative and might later prove to be wrong. He could reject the Martin-Bohonos product claim on other grounds, however, which were not applicable to Cyanamid's Boothe-Morton application. This he did, citing the Stephen's article which was a statutory bar to the product claim in Martin-Bohonos, but not to the claim in the Boothe-Morton application which was to be included in an interference.

The hearing examiner, by his theory that there is a difference in the law as to prior inherent production between product and process claims, is enabled thereby to dismiss two cases cited by Lidoff as involving process, not product claims. It must be noted at this point that the hundreds of pages of the file wrappers of various patent applications in the record reveal that Lidoff was thoroughly familiar with the patent law and it should not be easily inferred that he would cite a process case as precedent in rejecting a product claim unless

[27] See p. 1813 *supra* in this opinion.

the principle therein was equally applicable to both product and process claims. Furthermore, the hearing examiner, in characterizing the holding of *Allen* v. *Coe*,[28] misses the relevance of Lidoff's citation of that case, stating that it holds that what was claimed was obvious in the light of the disclosures of the prior patents. The hearing examiner concludes as to these cases:

Both of these cases hold that what was claimed was obvious in the light of the disclosures in the prior patents. No such theory is applicable to an undisclosed product present in a prior art mixture but unknown to anyone. Neither of these precedents were as much in point as *Cavallito*,[29] which involved an old known product with a newly discovered unknown component of the same utility.

Case Citations by the Patent Examiner

Contrary to the above conclusion of the hearing examiner, these two cases (*Allen* v. *Coe* and *In re Lieser*) strongly support complaint counsel's interpretation of Lidoff's ruling, *i.e. that a prior disclosure of a process which inherently produces a product is equivalent in patent law to a disclosure of the product itself and that the later identification of the product does not constitute an invention. Allen* v. *Coe* involved an application for a patent for a process of using spent distillers' grain mash in the production of yeast of a high vitamin content which could be used as a therapeutic product. A prior patent to one Bacon described the process of using rice polish and spent distillers' grain mash in manufacturing yeast. Bacon had described the use of rice polish to the extent of about seven percent of the total preparation, but gave no proportion for the spent distiller's mash. The claimants, Allen and others, found that by using spent distillers' mash in the proper proportions they could obtain a yeast of high yield with high vitamin content. The court held that the Bacon patent anticipated their claim by disclosing a process which inherently produced vitamins in the end product even though this was unappreciated in the prior art. The court said:

We agree with the lower court and with the Board of Appeals and the examiner that no invention is shown over Bacon. It may well be that Bacon did not appreciate the importance of vitamins in the final product; but he unquestionably pointed out the high vitamin content of spent distillers' mash and taught its use in the molasses mineral salts process of yeast manufacture. The fact that he used the spent mash for increasing the yield of yeast rather than for increasing its vitamin content is immaterial, since a patent may not be granted for scientific explanations or discoveries of new uses or for unsuspected merit in old substances or processes. [Citing cases.]

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[28] *Allen* v. *Coe*, 135 F. 2d 11 (D.C. Cir., 1943); *In re Lieser*, 162 F. 2d 224 (C.C.P.A 1947).

[29] [*Ex parte Cavallito*, 89 U.S.P.Q. 449 (Pat. Off. B'd App. 1950).]

The record is clear that Lidoff regarded the opinion as saying that the Bacon patent did not recognize the presence of vitamins in the final product so that it would disclose the yeast as a therapeutically useful product. We know this from Lidoff's citation of this case in connection with another legal issue that arose. In the dissolution of the second interference, in rejecting proposed fermentation counts on the basis of inherent production in the Duggar process, Lidoff stated:

> Duggar may not have *recognized* the presence of tetracycline in the fermentation broth, but he did recognize the antibiotic activity of the broth * * *. There is no invention over Duggar in the *recognition* of additional advantages in his fermentation process, under the doctrine expressed in *Allen* v. *Coe*, 135 F. 2d 11 * * *. (Emphasis added.)

The other case cited by Lidoff that was so lightly dismissed by the hearing examiner is *In re Lieser*, 162 F. 2d 224 (C.C.P.A. 1947). This case, as *Allen* v. *Coe*, supports our finding that Lidoff was relying on the theory that a prior patent could anticipate a later claim even though it did not "recognize" the significance of the inherent results of the process it discloses. In this case there was an application for a patent on cuprammonium cellulose spinning solutions produced by dissolving cellulose in ammoniacal copper compounds. A prior reference, a patent to Gulbrandsen and others, had covered the same process but had specified the temperature for the solution to be 0° to 20° C. The Gulbrandsen patent added to the disclosures therein: "Temperatures considerably lower than 0° to 20° C are highly advantageous." Lieser's application specified —7° or —8° C. The issue was whether Gulbrandsen's patent anticipated Lieser's alleged invention. The court held that it did, stating that the language in Gulbrandsen, et al., "fairly suggests the use of temperatures as low as —7° or —8° C., and it is, therefore immaterial whether the patentees anticipated that any particular desirable results would be obtained at those precise temperatures. *No invention is involved in following the teaching of the prior art, even if the results obtained are better than might have been expected.* [Citing cases.]" (Emphasis added.) The principle announced in this case was pertinent, notwithstanding the hearing examiner's conclusion to the contrary.

Lidoff, after citing the above two cases, then stated:

> It has long been held that a purer form of an old product is not inventive and the (apparent) mixture of the prior art meets the claims. (See Parke, Davis v. Mulford, 189 F. 95, and In re Kebrich, 96 U.S.P.Q. 411)

We have already explained our conclusion that *Parke-Davis* was cited by Lidoff for the general rule announced therein—that a purer form

of an old product is not inventive—and that this case supports also the second principle stated in the above-quoted sentence—that a mixture in the prior art would meet Conover's broad claim for "tetracycline". The hearing examiner has erroneously used another holding in *Parke-Davis* to support his belief that Lidoff's theory was that tetracycline was patentable if it could be demonstrated that any tetracycline present in commercial Aureomycin would not have imparted any degree of utility to the product. (Pages 88 and 89 of the Initial Decision)

The hearing examiner's handling of *In re Kebrich* also reveals how his preconceived notion of what the law *should be* as to the patentability of tetracycline has led him astray from the real issues: What was the ground of Lidoff's rejection of the Conover claim, and in overcoming that rejection, did Pfizer knowingly misrepresent or withhold material information? The hearing examiner characterizes *Kebrich* as follows:

> *Application of Kebrich* is a case where the court simply held that the claimed product had been disclosed in the prior art, a publication in the Chemical Journal. The Court held that the claimed product was substantially the same as that disclosed in the prior art. The Court distinguished and upheld *In re Williams*, considered next * * *.[30]

He then discusses *In re Williams*, 171 F. 2d 319 (C.C.P.A. 1948), and states that this case and still another not cited by Lidoff, "stand for the proposition we have here." He goes on to discuss *Williams* and shows how it supports the theory that tetracycline should be patentable. An analysis of *Kebrich*, however, reveals that it was accurately cited by Lidoff and that its holding is far more relevant to the instant case than the hearing examiner indicates. In *Kebrich* the court held that an application for the product dibasic lead stearate was anticipated by the description in a printed publication of dibasic lead stearate in mixture with monobasic lead stearate. The court held that as the applicant's claim was not limited to pure dibasic lead stearate it covered that product in any mixture and was thereby anticipated by the description in a printed publication. Thus, in the Conover application, "tetracycline" was broadly claimed and was not limited to any particular environment or degree of purity. Lidoff was saying in the last sentence of his rejection that the prior existence of tetracycline in the fermentation broth in mixture with Aureomycin would

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[30] The hearing examiner fails to appreciate the significance of how the court in *Kebrich* distinguished the *Williams* case. *Williams* was distinguished in *Kebrich* on the ground that the claim in that case was a narrow claim which excluded anticipation by a prior mixed compound. Kebrich, the court pointed out, was asserting a broad claim. Lidoff likewise was confronted by broad claims in Conover's application.

anticipate the broad claim for "tetracycline". Indeed, Pfizer's attorneys were well aware of this rule of law and understood Lidoff's statement. In the "Remarks" they filed on December 8, 1954, with the Tanner and Bogert affidavits they moved to amend their claims by adding narrower claims which covered tetracycline only in certain forms. Their reason was explained thusly:

> It was pointed out to him [Lidoff, during the previous interview] that there are substantial differences in scope between these two sets of claims, and that applicant should be granted claims 13 to 16 as insurance against some wholly unrecognized prior production of ineffective amounts of the products defined in claims 1 to 6. (CX 4, p. 39)[31]

This statement reveals another fact. It shows that Pfizer's attorneys understood that even small "ineffective" amounts of tetracycline in the Duggar and Niedercorn broths would be an anticipation of Conover's claim, and that Lidoff was not looking for only large quantities that would impart utility to the final commercial product.

In spite of the context of the citation of these cases by Lidoff, the hearing examiner summarizes them in the following manner:

> The fact that Lidoff cited the *Parke, Davis, supra, and Kebrich* decisions demonstrated that he was aware of the possibility that, even if the presence of tetracycline in the prior art product had been known and disclosed, it might be patentable if it possessed utility different in kind rather than degree from the prior art product. This was the teaching of those decisions. (p. 89)

The cases cited by Lidoff, as we have shown, do not support the above characterizations. Rather, they support the finding that Lidoff was interested in the inherent production of tetracycline in the fermentation broth in mixture with Aureomycin under the processes disclosed in the Duggar and Niedercorn patents. The hearing examiner's characterization of the cases is but a summary of what the hearing examiner, on the basis of other decisions, has concluded the law should be.

Additional Errors Contained in the Initial Decision

In support of his theory of the law, the hearing examiner states:

> The actual fact of inherent production, namely, that Aureomycin contained from 2 to 5% tetracycline, demonstrated beyond doubt that the utility of Aureomycin was not due to the presence of tetracycline, and hence that tetracycline was patentable. (p. 91.)

This reasoning cannot be accepted by the Commission. This question of utility was never raised by Lidoff or anyone else.

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[31] Claims 2 to 6 were the original claims for tetracycline and its various salts. Claim 1 was a Markush claim using tetracycline and its salts as subgeneric species.

Another misleading aspect of the hearing examiner's statement that Aureomycin contained from 2 to 5% tetracycline is that Lidoff was never informed of this fact by Pfizer. After he had examined the Tanner and Bogert affidavits, which stated that no tetracycline could be recovered from the broths, Lindoff granted a notice of allowance to Pfizer. Under Patent Office procedure, a patent normally issues within a month of such notice. Six days before the issuance of the Pfizer patent on January 11, 1955, Lidoff's division received an affidavit from Bristol (the Taylor affidavit) in connection with Bristol's Heinemann application, which stated that 2 to 4% of tetracycline had been found in Aureomycin products, including products that had been placed on the market before the date of the Conover discovery of tetracycline. The hearing examiner, at page 88 of his decision, uses this as the basis for his conclusion that Lidoff *knew* that tetracycline was inherently produced and *therefore* he must have ruled that this was not enough tetracycline in old Aureomycin products to impart utility thereto, otherwise he would have taken action to halt the issuance of the patent.

This reasoning cannot be accepted for several reasons. As explained in our Findings [32] the Taylor affidavit did not refute Pfizer's tests. In addition, Lidoff could not make reference to such an affidavit in rejecting the Conover claim since it was filed in a confidential *ex parte* proceeding. Bristol, in filing the Taylor affidavit, did not waive its right to secrecy in regard to its Heinemann application. Therefore, Lidoff, even if his suspicions had been aroused by the Taylor affidavit, could not have shown the basis thereof, since the only evidence in the Conover file wrapper was an affidavit by an apparently equally reputable scientist as Dr. Taylor which stated categorically that no tetracycline was recovered from the broth fermented with NRRL–2209.

In connection with the hearing examiner's reasoning that Lidoff *knew* that tetracycline was inherently produced to some extent, it should be pointed out that Lidoff, after the Tanner and Bogert affidavits were submitted to him (which the hearing examiner erroneously states conceded to the Patent Office that 10% tetracycline was present in Aureomycin) and after the Taylor affidavit had been received, withdrew his original rejection in another Pfizer process

[32] The Taylor affidavit did not constitute proof of inherent production of tetracycline in the Duggar and Niedercorn processes as disclosed in the prior art since the fact that tetracycline was contained in some commercial Aureomycin samples did not mean that its production was inherent or intrinsic in the processes in question using the NRRL–2209 microorganism which was the only one disclosed in the prior art. Respondents readily concede this latter point. See Paragraph 26 of our Findings.

application [33] and Pfizer received the patent on that process. The rejection in this application had been on the same ground on which Conover had been rejected—inherent production in the Duggar and Niedercorn processes. The hearing examiner neglects to explain how Lidoff "knew" that tetracycline was coproduced in the Duggar and Niedercorn processes in amounts up to 4%, 5% and 10% and at the same time allowed this process application.[34] The answer, of course, is that Lidoff did not know of coproduction in the prior art using the deposited microorganism NRRL–2209 and did not consider the Taylor affidavit as overcoming the Tanner and Bogert tests.

The hearing examiner's decision itself is inconsistent on the question of whether it was known to the Patent Office that tetracycline was coproduced if one followed the Duggar and Niedercorn processes. The initial decision at page 16 states that by the fall of 1953 it was general knowledge in scientific circles and the Patent Office that tetracycline was produced in Duggar and Niedercorn broths. This statement was made to support the finding that the Patent Office was interested only in whether the commercial product Aureomycin contained tetracycline as distinguished from the broth.[35] Yet at page 27 of his decision the hearing examiner finds that in response to a question by Lidoff, counsel for Cyanamid (Edelblute) filed in December 1953 a denial of any production of tetracycline by Cyanamid in its Aureomycin processes.[36] Also, he finds that on December 8, 1954, Pfizer filed an amendment and affidavits with the following statement:

> It was pointed out [at the last interview] to the Assistant Examiner that there is no reasonable basis for his speculation as to the coproduction of tetracycline in the prior art processes * * *. [T]here are no statements whatever in the Minieri et al. application to the effect that most strains of *Streptomyces aureofaciens* are capable of producing tetracycline under previously known fermentation conditions * * *. Minieri et al. themselves, in their brief on their motion to add fermentation counts in the interference * * * have stated that tetracycline could previously be produced only by deschlorination, and that there is no evidence of inherent production by the prior art processes. Most striking of all is the fact that the assignee of the Duggar and Niedercorn et al. patents,

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[33] The Bogert and Walsh application for a process of separating tetracycline from Aureomycin.

[34] As stated before at p. 36 *supra,* the hearing examiner reasons that Lidoff's rationale was that the coproduction of *any amount* of tetracycline would bar a process claim.

[35] The hearing examiner states that the fact that tetracycline was present in the resultant product, Aureomycin was not known at this time and did not become known until the Taylor affidavit was filed in the Heinemann application. The purpose of the Taylor affidavit, however, was to show that tetracycline was coproduced in the *broth,* as was so stated in the explanatory letter filed by Bristol. This shows that it was understood by Bristol that data as to coproduction in the broth was material information.

[36] See Paragraph 13 of the Findings, *supra.*

who manufactured literally tons of chlortetracycline (Aureomycin) according to the methods described therein, failed to discover any tetracycline in such large-scale manufacture, although it devoted extensive research to the recovery, purification and properties of its patented antibiotic.

Pfizer then argued the law:

It was further submitted to the Examiner that there is no proper basis in law for his rejection, even assuming that his speculation as to inherent co-production were correct. There are numerous court decisions establishing the rule "novelty is not negatived by any prior accidental occurrence or production, the character and function of which was not recognized until later than the date of the patented invention sought to be anticipated thereby". * * * It follows that a wholly unrecognized occurrence of some ineffective amount of tetracycline in a prior art product could not anticipate applicant's claims. (CX 34, pp. 34–6)

The Commission, on the basis of the record, cannot accept the hearing examiner's finding that by the fall of 1953 it was known by all, including Lidoff, that coproduction occurred in the Duggar and Niedercorn processes. The hearing examiner fails to understand that the fermentation applications submitted to Lidoff concerned processes which allegedly produced tetracycline for the *first time* by fermentation because they differed from the Duggar and Niedercorn processes in that they used an environment substantially free of chloride ions and used newly discovered microorganisms.[37]

The hearing examiner, in support of his conclusions, also uses the following reasoning: At page 89 of his decision he surmises that Lidoff must have wanted to know whether tetracycline could be *recovered* from the broth by recovery techniques, as distinguished from mere identification by analytical research techniques, so that he could then assume that tetracycline was present in such "substantial" quantities that it must have been recovered along with Aureomycin and was present in the end product in (again) "substantial" quantities so that it imparted utility thereto. The hearing examiner states that 10% of tetracycline in the end product would not have been "substantial". He then states: "This fact, and the later proof of from 2 to 5%, demonstrated that the prior product did not contain substantial quantities of tetracycline and, hence, the utility of the prior product was not due to the presence of tetracycline. In fact, the record establishes that tetracycline was an impurity in the prior art product and rather than contributing to its utility detracted from it." At another place he states: "The presence of only 2 to 5% tetracycline

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[37] Bristol argues that its other applications (*Lien, et al., Gourevitch, et al., Chertow,* and *Hatch, et al.,*) all disclosed the fact of coproduction. These, however, describe processes which utilized particular chloride-ion free conditions. See pp. 9 and 14 *supra* as to the significance of a chloride-free environment.

in Aureomycin would have established to him that it was not recoverable as a separate therapeutic product." The above statements are examples of how the *a priori* reasoning of the hearing examiner has forced him to overlook uncontroverted evidence and to distort the evidence he does rely on. The arguments from the initial decision quoted immediately above are fallacious for the following reasons: Contrary to the argument of the hearing examiner, the Taylor affidavit *did* show that tetracycline was *recovered* from Aureomycin (the commercial product) by the Craig countercurrent separation procedure. (CX 9, p. 179, Tr. 9263) This is ignored throughout the entire initial decision. Secondly, the record nowhere shows that tetracycline ever detracted from the utility of commercial Aureomycin. Thirdly, the record nowhere indicates that five percent (or any other particular percentage) tetracycline in the final commercial product would not impart some antibiotic utility to the whole product and to the contrary the record shows that even a small percentage of tetracycline in the final product would impart to it some antibiotic utility. (Tr. 4575)

The hearing examiner's explanation of why Lidoff wanted recovery tests used, as distinguished from nonrecovery analytical tests, is not supported by the record. The "Remarks" filed by Pfizer's attorneys simply state: "The Examiner made it clear he would not insist on a categorical averment that the fermentation broths prepared according to the cited patents contain no tetracycline whatsoever. He evidently appreciates the impossibility of proving its non-existence and is not concerned about useless trace amounts which cannot be separated from the broths by methods now recommended for recovery of the new antibiotic." (CX 4, p. 37) It is not necessary to speculate as to Lidoff's reason in having only recovery procedures used in the affidavit tests, since the record is clear that, whatever his reason may have been, Pfizer made false statements and withheld material information regarding the coproduction of tetracycline in recoverable quantities. Nevertheless, we think it is clear from the above explanation of the examiner's position that the purpose of the tests was to ascertain whether *any* tetracycline was coproduced and that the best and fairest means of determining this was to recover tetracycline in clearly identifiable form. The record indicates that positive identification of tetracycline is best established by recovery methods. (Tr. 9263–64)

Throughout his decision, the hearing examiner equates the following terms with one another—"recoverable quantities," "appreciable

quantities," and "substantial quantities." The record nowhere indicates that Lidoff used the term "substantial quantities" as signifying what he considered to constitute coproduction. Lidoff never used the term "appreciable quantities" in his rejections. This term was used only in the "Remarks" and affidavits filed by Pfizer in December 1954. Hutz, the author of the "Remarks," conceded on the witness stand that "appreciable quantities" was used synonymously with "recoverable quantities" and it is clear from the context in which the term was used that it was so intended. (Tr. 3627)

Constituting a necessary step in the hearing examiner's conclusion that no misrepresentation or withholding of information occurred is the hearing examiner's finding that Pfizer, in its Bogert affidavit, informed Lidoff that he could assume that the amorphous product Bogert recovered contained ten percent tetracycline. Examining the affidavit as a whole clearly reveals that Bogert merely stated that if this particular amorphous product contained no more than ten percent tetracycline, there would be no way of recovering it, because ten percent of the .36 grams of amorphous material of a potency of 260 micrograms per milligram would mean that no more than .009 grams of tetracycline was present and such a minute amount could not be separated and recovered. This simply meant that as to this particular amorphous material, he could not recover tetracycline if it were there in a quantity constituting ten percent or less of the antibiotic material therein. The hearing examiner reasons that Pfizer, by conceding that its scientists could not detect ten percent tetracycline if it were present in that amorphous product, thereby conceded to the Patent Office that there *was* ten percent present and ten percent present in *all Aureomycin.* (Pp. 66, 69 of Initial Decision)

The hearing examiner has made a serious error in reasoning that if ten percent of the amorphous product recovered by Bogert was tetracycline then this would establish that ten percent of the antibiotics produced in the broth was tetracycline and that ten percent of the commercial product Aureomycin was tetracycline. The hearing examiner fails to take into account the fact that the amorphous product resulted from a recovery procedure that was *selective* as to tetracycline, *i.e.*, the recovery procedure tended to isolate only tetracycline and leave substantial portions of other antibiotics such as chlortetracycline (Aureomycin) in the broth or in the filtrate. Assuming, for the purpose of illustration, that ten percent of the potency of the amorphous product was due to tetracycline and that the recovery technique left 95 percent of the total Aureomycin pro-

duced back in the broth or in the filtrate, then a simple calculation will show that the amount of tetracycline produced in the broth would be about one-half of one percent of the total antibiotic material. (Tr. 4456–60)[38]

Because of this error, the hearing examiner erroneously finds that the fact that 2 to 5% coproduction of tetracycline occurred would not have been of interest to Lidoff:

> The presence of only 2 to 5% tetracycline in Aureomycin would have established to him that it was not recoverable as a separate therapeutic product. This is further demonstrated by the fact that Pfizer requested the patent examiner to assume that as much as 10%, twice what the record reveals was present at most in old Aureomycin, was present in the amorphous product recovered from the test. In spite of this admission on the part of the applicant, the patent examiner promptly allowed the application. This demonstrates that knowledge of the presence of 2 to 5% tetracycline in old Aureomycin would have led him to the same conclusion. (I.D. at p. 62)

The hearing examiner concludes:

> No matter what fermentations were prepared or recovery methods applied, they could only have established at the most that the resultant product contained less than 10% tetracycline, the amount Pfizer requested the patent examiner to assume. Pfizer did not withhold or misrepresent any information concerning inherent production. (I.D. at p. 66)

VIII

FALSE STATEMENTS AND WITHHOLDING OF INFORMATION BY PFIZER

The Commission, contrary to the above conclusion of the hearing examiner, finds that Pfizer made false statements to the Patent Office and withheld material information. The record shows that Lidoff was not interested in ascertaining any particular percentage figure of coproduction but wanted to know whether tetracycline could be recovered in clearly identifiable form from any of the media described in the Duggar and Niedercorn patents using the deposited microorganism NRRL–2209. The record indicates that Lidoff believed that Example 28, because of its low chloride ion content, was the most favorable of the media in Niedercorn for the production of tetracycline. Pfizer had discovered from previous tests that little potency was obtained using NRRL–2209 in the Example 28 medium. Dr. Bogert, in October 1954, determined that higher potencies were obtained using Example 1 of Niedercorn and that tetracycline was

[38] Lidoff had no way of knowing the degree of selectivity. Since he was told that Procedure A was a "very efficient method for selective recovery" of tetracycline, he might well assume that the efficiency would be as high as stated above.

coproduced with Aureomycin.[39] Neither Bogert nor his superiors revealed this fact to the Patent Office. Bogert indicated in his monthly report to his superiors that tetracycline was known to exist in this type of broth and the evidence is undisputed that Bogert's tests were initiated at the request of Pfizer's patent officials. Although these officials deny they had knowledge of the results of Bogert's tests, they were under a duty to make inquiry before making the statement to the Patent Office that "The available evidence is overwhelmingly contrary to the Examiner's assumption."

The evidence of record also shows that Pfizer's representatives before the Patent Office withheld the fact that the test broths were unusually low in potency. The hearing examiner is in error in finding at page 65 that the weights and potencies of the recovered materials set forth in Bogert's affidavit made apparent the fact that the broths were low in potency. Since the recovery procedures employed by Bogert were to be selective as to tetracycline, Bogert's failure to recover anything but small amounts of amorphous material suggested to one not informed of the low antibiotic content of the broth that there was no significant production of tetracycline as compared to Aureomycin. The record clearly establishes that the potencies could not be calculated or reasonably estimated from information given to Lidoff. (Tr. 1912, 2869) In light of Hutz's testimony that great precautions were taken in conducting the tests and drafting the affidavits to make them invulnerable from attack in the forthcoming suit against Bristol, Squibb and Upjohn, it taxes credulity to believe that the omission of this important fact from the papers filed with the Patent Office was inadvertent. It is of interest to note that in the depositions taken during the infringement suit, Bogert testified that he thought that the broth potencies had been included in Tanner's affidavit and for that reason did not mention them in his. (CX 37, p. 114)

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[39] Subsequent tests run by Bristol using NRRL-2209 in the medium described in Example 1 of Niedercorn substantiate Bogert's previous findings that these potencies were much higher than those obtained in Pfizer's broths and that appreciable amounts of tetracycline were produced. For instance, the following exhibits show the potencies and the percentages of tetracycline estimated from paper chromatography:

RPEx	674-A	131 mcg/ml	5-10%
RPEx	674-A	163 mcg/ml	5-10%
RPEx	674-E	75 mcg/ml	20%
RPEx	674-F	245 mcg/ml	20%
RPEx	675-A	220 mcg/ml	5-15%
RPEx	678-E	216 mcg/ml	5-15%

Tanner obtained a potency of 75 mcg/1 ml. in his October experiment. The higher potencies obtained by Bristol may be due to the fact that the fermentations were run for longer periods of time.

Hutz and Murphy, Pfizer's patent representatives, claim that when they submitted the affidavits to Lidoff on December 8, they told him that NRRL–2209 was a poor producer and that the test broths had low potencies. They do not claim, however, that the actual potency figures were disclosed to Lidoff. Although Hutz or Murphy may have mentioned to him that NRRL–2209 was a relatively poor producer and was not the microorganism used by Cyanamid in its commercial production as they claimed they said, such a statement would not have been inconsistent with the representation that the test broth potencies were in the range of the potencies described in the Niedercorn patent. The Niedercorn potencies ranged from 109 to 396 micrograms of Aureomycin per milliliter, and commercial fermentation broths usually exceed 1,000 micrograms per milliliter. A casual remark to the effect that NRRL–2209 was a relatively poor producer and was not a commercially used microorganism would indicate only that it produced broths within the range of Niedercorn potencies or in the lower portion of this range. It certainly would not constitute disclosure of the fact that the potencies were between 5 and 7 micrograms per milliliter, a mere fraction of the Niedercorn broth potencies. Dr. Tanner (the Pfizer scientist who prepared the test broths), for instance, described similar broth potencies that he had obtained in September 1954 experiments as being "miserable". (CX 33, p. 180)

The record also shows that information concerning the pH of one of the test broths was withheld. In response to complaint counsel's proof that the pH of the Niedercorn broth during the first part of the tank fermentation exceeded the limits prescribed by Niedercorn and that this was not disclosed, the hearing examiner states that Tanner's affidavit specifically points out that the fermentation was adjusted to a pH of 6.7 because it was found to be higher than that recommended by Niedercorn. This is true, but what complaint counsel were attempting to show was that after the pH was thus adjusted, the medium was autoclaved (sterilized under pressure) and then *again* tested for pH. The test showed that the pH had risen to 8.1 and the medium was then inoculated and allowed to ferment for six and one-half hours even though this was at the limit of the range specified by Niedercorn and far outside the range recommended for optimum results. Contrary to what the hearing examiner indicates, the pH values during fermentation were not disclosed.

During the trial of this case, it was discovered by Cyanamid's research personnel that a typographical error was made in the Niedercorn patent and that ten times as much ammonium hydroxide was

specified than was intended by Niedercorn and that this undoubtedly caused the high alkalinity. There is no proof that the high pH necessarily altered the end results of the experiment on broth 1771B. It may or may not have done so. Tanner did know, however, from his previous experiments with Niedercorn Example 28 that the pH could be expected to be too high and would have to be adjusted at some point. Furthermore, he related this fact to Dr. Murphy, who, together with Hutz, drafted Tanner's affidavit. (CX 34, pp. 57–58) Tanner, when questioned about this matter during the Bristol-Pfizer discovery proceedings, testified as follows:

Q. Did you have any discussion with anybody as to whether these pH's would be stated in the affidavit?

A. No. I presumed they would be. (CX 33, p. 239)

Pfizer's apparent purpose in withholding the above information was to put the affidavit tests in the best possible light so as to avoid the possibility that further tests would have to be made. Withholding of this information gave further credence to the impression the affidavits and accompanying papers conveyed to the patent examiner; namely, that the test broth potencies were within the general range of potencies described in the Niedercorn patent, and that no further tests need be conducted using Duggar and Niedercorn media.

The record also establishes that other procedures were available to Pfizer's scientists for recovering tetracycline in clearly identifiable form and that this fact was not disclosed to the patent examiner. Pfizer argues that the examiner would not have required these procedures as they were not commercial-type procedures. There is no indication in the summaries or oral interviews that he limited the recovery techniques to commercially feasible procedures. Although he did not require Pfizer to engage in "an elaborate research program" it was understood by Pfizer's representatives that this meant that Pfizer was not required to develop *new* recovery techniques. The very fact that Lidoff wanted an explanation of why Dr. Bogert did not make further attempts to isolate tetracycline from the minute amorphous products recovered from the test broths reveals that he did not specify that only commercial procedures be utilized.

The Testimony of the Expert Witnesses

Pfizer argues that the expert witnesses testifying for counsel supporting the complaint made a "complete about face" when brought back for rebuttal testimony after hearing respondents' scientists testi-

fy. Pfizer, for instance, argues that Dr. Benedict [40] admitted on rebuttal that in following the Duggar and Niedercorn examples using the NRRL–2209 microorganism, he or any other skilled scientist would be more likely to produce broths having no potency than broths having the potencies obtained by Dr. Tanner. We cannot agree with this interpretation of Dr. Benedict's testimony. Dr. Benedict was examining various fermentations conducted by Bristol using Duggar and Niedercorn Example 28 media —not fermentations of *all* Niedercorn media. (Tr. 10,952–54, 10,970–72)

Bristol's records showed that 23 out of 26 tests using the NRRL–2209 in Duggar medium resulted in no potency and that three resulted in having potencies of 30, 37 and 37 mcg/ml. Bristol also performed eight tests using Niedercorn 28 and seven of these produced no potency and one produced a potency of 85 mcg/ml. As noted before, Bristol also conducted a number of tests employing Niedercorn Example I and obtained substantially greater potencies. The significance of the distinction between Duggar and Niedercorn Example 28 on the one hand and Niedercorn I on the other is pointed up by Dr. Benedict's answer to the following question posed by the hearing examiner:

> Based upon the tests that Bristol conducted that we have discussed at some length here, in your opinion as a scientist, would they have reason to believe, based upon that information which they had before them, that there was anything wrong with the tests conducted by Bogert and Tanner, and the information given the Patent Office?
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> * * * * * * *
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> [Dr. Benedict:] I think, your Honor, that what these experiments imply to me is the fact that Bristol was able to show by using Niedercorn No. 1 that appreciable quantities of tetracycline were co-produced with Aureomycin. I think that is quite emphatically pointed out here. They have also shown, of course, that in most cases they got nothing when they ran the Niedercorn and Duggar, rather than the [sic: rather the] Example 28 and the Duggar examples, and that to me is the significance of this. (Tr. 11,021)

Pfizer next argues that Dr. Benedict admitted on rebuttal that the pH of Tanner's broth did not depart from the instructions of Niedercorn Example 28. Another part of the Niedercorn patent, however, clearly gives the pH ranges for all the Niedercorn examples. Benedict was merely testifying that nothing was said in Example 28

[40] Dr. Robert Glen Benedict obtained his Ph. D. in Agricultural Bacteriology from the University of Wisconsin in 1936. In 1942 he joined the Northern Regional Laboratory of the United States Department of Agriculture where he was engaged in various types of research work involving antibiotics and fermentations. Dr. Benedict has authored about forty publications.

to show whether the pH should be adjusted *before or after* sterilization. (Tr. 10,971) The significance of Tanner's pH was that it was allowed to remain at or slightly above the uppermost limit specified by Niedercorn and this fact was not disclosed. The Tanner affidavit implied that the pH was maintained in the optimum range (at 6.7, midway between 6.4 and 7.0) for the entire fermentation period.

Pfizer also argues that Dr. Stodola,[41] a witness for complaint counsel, agreed on rebuttal that the Craig countercurrent procedure could not be applied to fermentation broths and that he knew of no chromatography procedure available prior to Conover's discovery which was suitable for recovering tetracycline from fermentation broths. Pfizer's argument has no relevance to the issues, however. No one contends that the Craig procedure is applied *directly* to fermentation broths. Rather, it is applied to solid products recovered from the broths. (Tr. 11,041–42) Furthermore, the evidence is undisputed that Lidoff did not require pre-Conover or "prior art" types of recovery procedures, but required the use of any procedures currently known to be suitable for recovering and isolating tetracycline.

Pfizer points out that Stodola also agreed that the ratio of tetracycline to Aureomycin is more important than the total antibiotic potency of the broth in determining whether tetracycline can be recovered. This, however, in no way detracts from the evidence that where tetracycline constitutes a fixed percentage, such as five to ten percent of the antibiotic material, it is easier to recover tetracycline from a higher potency broth than from a lower potency broth. (See e.g., Tr. 11,031)[42]

Pfizer next argues that Dr. Stodola repudiated his former testimony by stating on rebuttal that the procedures used by Dr. Bogert were good ones for recovering tetracycline from the fermentation broths, and that they were the very procedures he would have selected. This is a distortion of Stodola's testimony. He merely testified that one or more of these methods could be used initially to concen-

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[41] Dr. Frank H. Stodola received his Ph. D. in organic chemistry from the University of Minnesota. He worked under a fellowship at Yale University from 1934 to 1937, and at the Kaiser Wilhelm Institute for Biochemistry from 1937 to 1938, and at the Mayo Clinic and Columbia University in following years. In 1942 he joined the Northern Regional Laboratory of the United States Department of Agriculture where he was put in charge of the Chemistry Section of the Fermentation Division. Dr. Stodola's work is primarily in the isolation, characterization, and structure determination of new fermentation products, and he is an expert on the isolation and separation of antibiotics.

[42] The hearing examiner at page 63 of his decision incorporates Dr. Stodola's statement as a finding without mentioning this fact. This finding, standing alone, gives an erroneous impression.

trate the antibiotics in Tanner's broths into crude form. (Tr. 11,042) He clearly pointed out that due to the low potency of these broths the tetracycline would not be directly isolated but that further purification and isolation procedures would have to be used. (Tr. 1943–46; 11,052) There is no inconsistency in this and his earlier testimony to the effect that Bogert's procedures were not designed to directly isolate tetracycline from the broths of the potencies obtained by Tanner.

Pfizer representatives intentionally created several false impressions in the papers filed with the patent examiner. One of these was their statement that the available evidence was contrary to the examiner's speculation that tetracycline had been produced in Aureomycin fermentations. This conveyed the definite impression that any tests that Pfizer had performed gave negative results. In fact, the same Pfizer scientists who conducted the affidavit tests for the Patent Office had earlier obtained positive results that coproduction did occur in one of the prior art processes. Pfizer's representatives before the Patent Office deny that they had knowledge of these tests. They do not claim, however, that they made any effort to ask these Pfizer scientists if they had ever found evidence of coproduction.

Where fraud in the procurement of a patent has been alleged in infringement suits and cancellation proceedings, the courts have stated that it must be established by clear and convincing evidence that the false or misleading statement was made (or information was withheld) deliberately and with intent to deceive.[43] Also, of course, the information that is misrepresented or withheld must be material.[44]

In order for the government to prosecute successfully a suit for patent cancellation, common law fraud must be proven. From an examination of the record as a whole, Pfizer's conduct before the Patent Office in misrepresenting and withholding certain information would warrant a judgment for cancellation. *But we do not find such a holding necessary to our disposition of the case.* Rather, we conclude that such conduct at the very least amounted to "unclean hands",

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[43] *United States* v. *American Bell Telephone Co.*, 167 U.S. 224 1897; *Haloro, Inc.* v. *Owens-Corning Fibreglas Corporation*, 266 F. 2d 918 (D.C. Ct. App. 1959); *Huszar* v. *Cincinnati Chemical Wks.*, 172 F. 2d 6, 11 (6th Cir., 1949); *Martin* v. *Ford Alexander Corp.*, 160 F. Supp., 670 (S.D. Cal. 1958); *United States* v. *Standard Electric Time Co.*, 155 F. Supp. 949 (D. Mass. 1957); *Marks* v. *Polaroid Corporation*, 129 F. Supp. 243 (D Mass. 1955), *aff'd.* 237 F. 2d 428 (1st Cir. 1956).

[44] *Hazel-Atlas Co.* v. *Hartford-Empire Co.*, 322 U.S. 238 (1944). See *Admiral Corp.* v. *Zenith Radio Corp.* 296 F. 2d 497 (10th Cir., 1961) where the court implied that a higher duty to disclose exists where the information is not accessible to the Patent Office.

"inequitableness" and "bad faith." [45] Under these circumstances, to allow Pfizer to raise its patent as a shield against the antitrust laws would be a blatant distortion of the purpose behind the patent laws. That the public should receive something new and useful from the holder of a patent is manifestly clear. And in this case Pfizer was clearly unwilling to reveal material information bearing on whether or not the public was in fact receiving the above benefits.

We hold that under the circumstances it was an act of deliberate misrepresentation of fact and suppression of information for the Pfizer patent officials to claim that the "available evidence is overwhelmingly contrary" to the examiner's assumption without having made any effort to ask Pfizer officials and scientists whether such assertion was correct. These Pfizer officials could not close their eyes to evidence which was close at hand which belied their statement.

Although it is impossible to determine for certain what would have occurred had Pfizer chosen to disclose all the information it had—the coproduction of tetracycline in Niedercorn Example I and the unusually low potency of the test broths—it can be reasonably inferred that Lidoff would have required a duplication of Niedercorn Example I and that Pfizer scientists could have recovered tetracycline from

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[45] In *Precision Instrument Manufacturing Co., et al.* v. *Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), 814, 819, Justice Murphy noted doctrines of equity which we think are applicable here:

The guiding doctrine in this case is the equitable maxim that "he who comes into equity must come with clean hands." This maximum is far more than a mere banality. It is a self-imposed ordinance that closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant. That doctrine is rooted in the historical concept of court of equity as a vehicle for affirmatively enforcing the requirements of conscience and good faith. This pre-supposes a refusal on its part to be "the abettor of iniquity." *Bein* v. *Heath* 6 How. 228, 247, 12 L. Ed. 416. Thus while "equity does not demand that its suitors shall have led blameless lives," *Loughran* v. *Loughran*, 292 U.S. 216, 229, 54 S. Ct. 684, 689, 78 L. Ed. 1219, as to other matters, it does require that they shall have acted fairly and without fraud or deceit as to the controversy in issue. *Keystone Driller Co.* v. *General Excavator Co.*, 280 U.S. 240, 54 S. Ct. 146, 147, 78 L. Ed. 293; *Johnson* v. *Yellow Cab Transit Co.*, 321 U.S. 383, 387, 64 S. Ct. 622, 624, 88 L. Ed. 814; 2 Pomeroy, Equity Jurisprudence (5th Ed.) §§ 397–399.

More specifically on the patent phase, the Court held that:

* * * Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the applications in issue. *Cf. Crites, Inc.* v. *Prudential Ins. Co.*, 322 U.S. 408, 415, 64 S. Ct. 1075, 1079, 88 L. Ed. 1356. This duty is not excused by reasonable doubts as to the sufficiency of the proof of the inequitable conduct nor by resort to independent legal advice. Public interest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies. Only in that way can the Patent Office and the public escape from being classed among the "mute and helpless victims of deception and fraud." *Hazel-Atlas Glass Co.* v. *Hartford-Empire Co., supra*, 322 U.S. 246, 64 S. Ct. 1001, 88 L. Ed. 1250.

such a fermentation broth. But it is not really necessary to determine what would have occurred had Pfizer not made misleading statements and had disclosed the information, as long as the statements and the information withheld were material to the examiner's determination of the patentability of tetracycline. *Hazel-Atlas Co.* v. *Hartford-Empire Co.*, 322 U.S. 238 (1944).

IX

ALLEGED FALSE STATEMENTS AND WITHHOLDING OF INFORMATION BY CYANAMID AND BRISTOL

In addition to the misleading statements and withholding of material information made by Pfizer, the record shows that various statements denying concomitant production were made by Edelblute, Cyanamid's patent attorney, to examiner Lidoff both before and during the second interference in connection with Cyanamid's Boothe-Morton and Minieri applications. These statements made Pfizer's failure to recover tetracycline seem all the more plausible. The record shows that Cyanamid, as early as December 1953, had evidence that tetracycline was present in its Aureomycin products and that this information was not disclosed to the patent examiner. (CX 81) [46]

Similar tests on commercial Aureomycin made by the other respondents substantiate Cyanamid's findings. Pfizer had subjected a capsule of Aureomycin to a Craig countercurrent in the fall of 1954 and determined by that method and by paper chromatography that tetracycline constituted 2 to 4 percent of the many samples tested. Squibb's laboratories analyzed commercial Aureomycin and concluded that it contained about 5 to 10 percent tetracycline. Upjohn analyzed a sample of Cyanamid's Aureomycin and found it to contain a 3.5 to

[46] Commission exhibit 81 is a Cyanamid interoffice memorandum which states in part: "A further search of our records indicates that we submitted a considerable number of production samples, dating back to early 1949, to Mr. Martin during December, 1953, with a request for chromatographic analysis for tetracycline. Verbal reports from him during the latter part of December, 1953, qualitatively established the presence of tetracycline in both current and early Aureomycin. This would appear to have been our first definite knowledge of the contamination of product crystals by tetracycline."

In February of 1954, copies of a memorandum containing the information that four samples of Aureomycin contained one to six percent tetracycline were distributed to various officials. It states on the memorandum that a copy was sent to Edelblute. (CX 111B) Edelblute, therefore, knew of or had ready access to information which contradicted his previous assurances to the examiner that tetracycline was not produced in the manufacture of Aureomycin. Edelblute denies that he received a copy of this memorandum. This would not excuse Cyanamid, however, from failing to correct the false statements. Furthermore, by his own admission, he knew of the fact of coproduction by December 1954. At this time, Cyanamid's and Pfizer's applications were still pending before the patent examiner and he had opportunity at that time, at least, to correct the record. He failed to do so, however, until many months after the Pfizer patent was issued.

4 percent tetracycline. The tetracycline content was confirmed by Craig countercurrent analysis.

As a result of Cyanamid's withholding of the truth, Pfizer was aided in its endeavor to convince the patent examiner that tetracycline was a new product and did not exist in the prior art. Although disclosure by Cyanamid of the presence of tetracycline in commercial Aureomycin would not conclusively have proven the existence of recoverable amounts of tetracycline in NRRL–2209 fermentation,[47] it is obvious that the categorical denial by Cyanamid of the coproduction of tetracycline strengthened Pfizer's position.

Cyanamid argues that it was under no duty to correct the statements made by its patent attorney because it appeared that the examiner withdrew from his position (regarding the relevance of inherent production) by reason of the declaration of the second interference in February of 1954. This does not afford Cyanamid an excuse to allow false statements to remain on record. Edelblute's statement (in response to an inquiry by Examiner Lidoff) that Cyanamid's tests revealed that no tetracycline was concomitantly produced might well have been a factor in the examiner's withdrawal from that position.[48] Moreover, Rule 237 of the Patent Office Rules of Practice makes it clear that the determination of patentability in declaring an interference is not conclusive and may be reversed by the examiner. Edelblute was obviously aware of this possibility since he reassured the examiner on two occasions during the second interference that inherent production did not occur. (CX 12, pp. 36, 381–83).[49]

Cyanamid's acceptance of a license in January of 1955 under the newly issued Conover patent with the knowledge that it made false statements of fact to the Patent Office and that these statements bore directly on the question of patentability of tetracycline, constituted an illegal attempt on its part to share in a monopoly on tetracycline. If, before the dissolution of the second interference, Cyanamid had corrected the record and had disclosed the information it had concerning inherent production, Pfizer undoubtedly would have been deterred from attempting to convince the examiner that tetracycline could not be recovered from the prior art broths. Moreover, Pfizer

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[47] Cyanamid representatives testified that the NRRL–2209 microorganism deposited by Cyanamid was not used in commercial operations.

[48] Cyanamid's argument that Edelblute's statement could not have influenced Lidoff since Lidoff "later" rejected Bristol's Heinemann claims on inherent production is without substance. The record shows that Lidoff's division of the Patent Office did not even receive Edelblute's statement until the day before Heinemann's rejection was mailed out. (CX 5, p. 44)

[49] By this time Cyanamid had performed numerous tests, all of which consistently showed that tetracycline, contrary to Edelblute's statement, was inherently produced. (CX 81, 79A, 80, 110 B, 111 A & B, 114)

would not have been able to state to Lidoff that: "The available evidence is overwhelmingly contrary to the Examiner's assumption * * *. Most striking of all is the fact that the assignee [Cyanamid] of the Duggar and Niedercorn, et al. patents, who manufactured literally tons of chlortetracycline (Aureomycin) according to the methods described therein, failed to discover any tetracycline in such large scale manufacture * * *."

Complaint counsel also charge Bristol with making false statements of fact to the Patent Office and withholding material information. We cannot agree that the evidence sustains the charge that Bristol made false statements or was under a clear duty to disclose the information it had concerning inherent production. Bristol's attorneys never denied coproduction but simply argued that the Duggar and Niedercorn patents did not disclose this fact.

X

APPLICABILITY OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

A

At various times in this proceeding, Pfizer, Cyanamid, and Bristol have taken the position that this Commission lacks jurisdiction to make inquiry as to the methods used to obtain the Conover patent. This contention, as it is set forth in Pfizer's brief, is based primarily upon 28 U.S.C. Sec. 1338(a), which provides that:

> The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, copyrights and trademarks. Such jurisdiction shall be exclusive of the courts of the states in patent and copyright cases.

Pfizer's argument, as we understand it, is twofold: (1) Since Congress has expressly given Federal courts original jurisdiction exclusive of state courts over civil actions arising under any Act of Congress relating to patents, Congress has by implication given Federal courts exclusive jurisdiction vis-a-vis all other tribunals, including the Federal Trade Commission; and, alternatively, (2) since Congress, in enacting the Federal Trade Commission Act, did not expressly confer jurisdiction over patent matters, this Commission lacks authority under the law to question the validity of a United States patent. Pfizer attempts to bolster the first of these two arguments by quoting dictum in *United States* v. *American Bell Telephone*, 128 U.S. 315 (1888), to the effect that the Federal courts alone can annul or cancel a patent issued by the Commissioner of Patents.

Pfizer's arguments fail to take into account the judicial interpretation of 28 U.S.C Section 1338(a) and other pertinent Supreme Court decisions. Moreover, the *American Bell Telephone* case involved an action in the nature of an *in rem* proceeding to cancel a patent obtained by fraud. This proceeding is of a different nature; it is grounded on the allegation in the complaint that respondents have committed unfair acts of competition in violation of the Federal Trade Commission Act. The distinction is one not without meaning. Cf. *Becher* v. *Contoure Laboratories, Inc.*, 279 U.S. 388 (1929) and *United States* v. *U.S. Gypsum Co.*, 333 U.S. 364 (1948), discussed below. That the legitimacy of the actions of Pfizer and Cyanamid before the Patent Office is drawn into question does not, in our opinion, deprive this Commission of jurisdiciton to issue an appropriate cease and desist order.

Section 1338(a) of the Judiciary Code of 1948 merely adopted language used for the first time in U.S. Rev. Stat. 134, Sec. 711(s) (1878). Since the Federal Trade Commission, as well as other quasi-judicial agencies, were created in later years, no inference can be drawn from the statute that Congress made federal court jurisdiction of actions arising under patent laws exclusive of this Commission as well as state courts. Furthermore, the "exclusive" jurisdiction given to federal courts has by no means completely circumscribed the power of state courts to decide cases involving patents. State courts have jurisdiction to rule on the validity of patents when the issue is incidental or collateral to the plaintiff's cause of action. *Pratt* v. *Paris Gas Light & Coke Co.*, 168 U.S. 255 (1897); *American Well Works Co.* v. *Lane & Bowler Co.* 241 U.S. 257 (1916); *MacGregor* v. *Westinghouse Electric & Mfg. Co.*, 329 U.S. 402 (1947). In one case a state court entertained a bill asking for assignment of a patent to the plaintiff, based on the claim that the defendant took the invention from the plaintiff in breach of trust and illegally obtained the patent in his own name. Although such a fact, if established, would constitute fraud on the Patent Office, the Supreme Court upheld the state court's jurisdiction to make this finding. In so holding, the Court enunciated the following principle which we think is apropos to this proceeding:

> That decrees validating or invalidating patents belong to the Courts of the United States does not give sacroscanctity to facts that may be conclusive upon the question in issue. A fact is not prevented from being proved in any case in which it is material, by the suggestion that if it is true an important patent is void. *Becher* v. *Contoure Laboratories, Inc.*, 279 U.S. 388, 391 (1929).

We conclude from the above precedents that there is nothing within 28 U.S.C. Sec. 1338(a) which would prevent this Commission from investigating unfair methods of competition before the Patent Office.

B

While it has been argued that the grant of a monopoly is an exception in an unrestrained free enterprise system,[50] it is an exception which has been anticipated by the Framers of the Constitution.

The Patent-Copyright Clause, Article I, Sec. 8, provides:

> Congress shall have Power * * * To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

The relevant federal statutes are contained in the Patent Code of 1952, 66 Stat. 792, 35 U.S.C. Sec. 1–293. With similar constitutional authority enabling it to regulate commerce, Congress has enacted the antitrust laws. In a landmark case, *United States* v. *Line Material Co., et al.*, 333 U. S. 287, 308, 309 (1948), the Supreme Court has articulated the relationships between these two laws:

> Thus we have a statutory monopoly by the patent law, and by the Sherman Act a prohibition not only of monopoly or attempt to monopolize but of every agreement in restraint of trade. Public policy has condemned monopolies for centuries [cases cited]. Our Constitution allows patents, Article I, Sec. 8, Cl. 8.
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> The progress of our economy has often been said to owe much to the stimulus to invention given by the rewards allowed by patent legislation. The Sherman Act was enacted to prevent restraints of commerce but has been interpreted as recognizing that patent grants were an exception. *Bement* v. *National Harrow Co., supra,* 92 91 Cong. Rec. 2457. Public service organizations, governmental and private, aside, our economy is built largely upon competition in quality and prices. *Associated Press* v. *United States,* 326 U.S. 1, 12–14. Validation by Congress of agreements to exclude competition is unusual. Monopoly is a protean threat to fair prcies. It is a tantalizing objective to any business compelled to meet the efforts of competitors to supply the market.

And the words of Judge Learned Hand precisely parse the philosophy behind the antimonopoly legislation:

> Throughout the history of these statutes [the antitrust laws] it has been constantly assumed that one of their purposes was *to perpetuate and preserve for its own sake* and in spite of possible cost, an organization of *industry in small units which can effectively compete with each other.*" *U.S.* v. *Aluminum Co. of America,* 148 F. 2d 416, 429 (2nd Cir. 1945).

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[50] "With us free enterprise is the rule, the grant of patent for invention or discovery the exception." *Patents and Free Enterprise* TNEC Monograph No. 31, p. 158 (1941). See generally — Hamilton, *Common Right, Due Process and Antitrust,* 7 Law & Contempt. Prob. 24 (1940).

This agency also has its very roots planted in that philosophy so precisely phrased by Judge Hand. Indeed, there is a breadth and scope to the meaning of "unfair methods of competition" which may be unduplicated in the entire administrative process.[51] Obviously, it is difficult to define the limits or to articulate with precision the meaning of unfair methods of competition. But this was the very thrust of the congressional purpose. The framers of the Federal Trade Commission Act envisoned its breadth and purposefully left flexible the catalog of offenses to be encompassed under this broad statutory mandate.

The 1914 Committee Report containing the recommendation that "unfair methods of competition" be prohibited emphasizes this point:

> One of the most important provisions of the Bill [S. 4160] is that which declares unfair competition in commerce to be unlawful, and empowers the Commission to prevent corporations from using unfair methods of competition in commerce by orders issued after hearing * * *.
>
> The Committee gave careful consideration to the question as to whether it would attempt to define the many and variable unfair practices which prevail in commerce and to forbid [them] * * * or whether it would, by a general declaration condemning unfair practices, leaving it to the Commission to determine what practices were unfair. It concluded that the latter course would be better, for the reason as stated by one of the representatives of the Illinois Manufacturer's Association, that there were too many unfair practices to define, and after writing 20 of them into law it would be quite possible to invent others.
>
> It is believed that the term "unfair competition" has a legal significance which can be enforced by the Commission and the courts, and that it is no more difficult to determine what is unfair competition than it is to determine what is a reasonable rate or what is an unjust discrimination. The committee was of the opinion that it would be better to put in a general provision condemning unfair competition than to attempt to define the numerous unfair practices such as local price cutting, interlocking directorates and holding companies intended to restrain substantial competition.[52]

Though every Sherman Act violation is encompassed within the scope of "unfair method of competition," [53] and since all unfair meth-

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[51] In the words of Professor Jaffe the Federal Trade Commission was "a landmark in legislation because it subjected business in general rather than a limited area such as transportation, gas, or electricity to administrative process"; Jaffe, *Cases on Administrative Law*, Introduction 10 (1954). See also Jaffe & Nathanson *Cases on Administrative Law*, Introduction 13 (1961).

[52] S. Rep. 597, 63d Cong. 2d Sess. (1914) at 13. Later the "Covington Bill" was referred to this same Committee which recommended that the "Newlands Bill" be substituted for it.

[53] With respect to jurisdiction, there is, of course, a difference in the "Commerce" requirements of the two statutes. The Supreme Court over 20 years ago held that the Sherman Act comprehended those restraints of trade which "affected interstate commerce". On the other hand, the Court stated that the Federal Trade Commission Act was limited to those unfair methods of competition which occurred "in commerce". See *Federal Trade Commission* v. *John Bunte & Bros., Inc.*, 312 U.S. 349 (1941). The validity of this distinction is not material to this decision.

ods of competition are not necessarily Sherman Act violations, this Commission's *original* jurisdiction is clearly not restricted to these offenses which have been adjudicated to be violations of the Sherman Act. And the Supreme Court has persistently reiterated this theme and resisted all attempts to establish a comprehensive itemized list of unfair methods of competition. In *Federal Trade Commission* v. *Cement Institute, et al.*, 333 U.S. 683 (1948) Justice Black has met squarely the issue of the breadth of the Commission's jurisdiction: [54]

* * * this court has pointed out many reasons which support the interpretation of the language "unfair methods of competition" in Section 5 of the Federal Trade Commission Act as including violations of the Sherman Act. Thus it appears that soon after its creation the Commission began to interpret the prohibitions of Section 5 as including those restraints of trade which also were outlawed by the Sherman Act, *and that this court has consistently approved that interpretation of this Act.* (Emphasis added.) (333 U.S. at 691.)

* * * * * * *

We adhere to our former rulings. The Commission has jurisdiction to declare that conduct tending to restrain trade is an unfair method of competition even though the self same conduct may also violate the Sherman Act.

There is a related jurisdictional argument pressed by Marquette which may be disposed of at this time. * * * Marquette and 88 other cement companies * * * [have been charged with] violating Section 1 of the Sherman Act * * * Marquette urges that the Commission proceeding should now be dismissed because it is contrary to the public interest to force respondents to defend both a Commission proceeding and a Sherman Act suit based largely on the same alleged misconduct.

We find nothing to justify a holding that the filing of a Sherman Act suit by the Attorney General requires the termination of these Federal Trade Commission proceedings. In the first place, although all conduct violative of the Sherman Act may likewise come within the unfair trade practice prohibitions of the Trade Commission Act, the converse is not necessarily true. *It has long been recognized that there are many unfair methods of competition that do not assume the proportions of Sherman Act violations. Federal Trade Commission* v. *R. F. Keppel & Bro.*, 291 U.S. 304; *Federal Trade Commission* v. *Gratz*, 253 U.S. 421, 427. Hence a conclusion that respondents' conduct constituted an unfair method of competition does not necessarily mean that their

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[54] The context for this discussion was set out as follows by Justice Black:

"Marquette contends that the facts alleged in Count I do not constitute an unfair method of competition within the meaning of Section 5. Its arguments run this way: Count I in reality charges a combination to restrain trade * * * Section 4 of the Sherman Act provides that the Attorney General shall institute suits under the Act on behalf of the United States and that the Federal district courts shall have exclusive jurisdiction of such suits. Hence, continue respondents, the Commission, whose jurisdiction is limited to "unfair methods of competition" is without power to institute proceedings or to issue an order with regard to the combination in restraint of trade charged in Count I." *Federal Trade Commission* v. *Cement Institute, et al., supra,* at 689–90.

same activities would also be found to violate Section 1 of the Sherman Act. In the second place the fact that the same conduct may constitute a violation of both Acts in nowise requires us to dismiss this Commission proceeding. * * * Both the legislative history of the Trade Commission Act and its specific language indicate a congressional purpose, not to confine each of these proceedings within narrow, mutually exclusive limits, but rather to permit the simultaneous use of both types of proceeding. Marquette's objections to the Commission's jurisdiction are overruled. (Emphasis added.) (333 U.S. at 693-95.)

As we initially stated, the monopoly granted by the patent laws is a clear but narrow exception to our free enterprise system. The thought that monopoly power may be acquired through fraud,[55] unclean hands, inequitableness or bad faith,[56] or any borderline behavior before the Patent Office [57] has manifest connotations of unfairness. Ironic indeed would be the result if this Commission—with power against partial, incipient and various other hybrid monopolies—could not arrest the continuance of an absolute monopoly procured by unfair methods.

Again in *Fashion Originators Guild* v. *F.T.C.*, 312 U.S. 457, 466 (1941), the court pointed out:

Petitioners, however, argue that the combination cannot be contrary to the policy of the Sherman and Clayton Acts since the Federal Trade Commission did not find that the combination fixed or regulated prices, parcelled out or limited production, or brought about a deterioration in quality. But action falling into these three categories does not exhaust the types of conduct banned by the Sherman and Clayton Acts. *And as previously pointed out, it was the object of the Federal Trade Commission Act to reach not merely in their fruition but also in their incipiency combinations which could lead to these and other trade restrainst and practices deemed undesirable.* (Emphasis added.)

For 75 years, the right of the United States to obtain cancellation of a patent procured by fraud has been clearly established.

That the government authorized both the Constitution and the statutes to bring suits at law and in equity, should find it to be its duty to correct this evil, to recall these patents, to get a remedy for this fraud is so clear that it needs no argument * * *. (*United States* v. *American Bell Telephone*, 128 U.S. 315, 370 (1888).

While admittedly respondents' actions may constitute a violation subject to prosecution by more than one governmental party, contrary

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[55] See *Hazel-Atlas Glass Co.* v. *Hartford-Empire Co.*, 322 U.S. 246 (1943).

[56] See *Precision Instruments Mfg. Co., et al.*, v. *Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945).

[57] See *U.S.* v. *The Singer Manufacturing Company*, 31 U.S. L. Week 4674 (U.S. June 17, 1963).

to respondents' urging, clearly our action is neither a pre-emption nor usurpation of the Attorney General's right to file suit for cancellation.

It is also evident to us that the bringing of the instant case represents no revolutionary theory. Over the past quarter century the Justice Department, in a series of landmark cases, has attacked the *abuse* of patent monopolies, alleging that the grant from the government had been utilized in such a way as to contravene the antitrust laws. See *United States* v. *Masonite Corp.*, 316 U.S. 265 (1942); and *United States* v. *Line Material Co., et al.*, 333 U.S. 287 (1948).

In *United States* v. *United States Gypsum Co., et al.*, 333 U.S. 364 (1948), the government had filed a complaint charging violations of Sherman 1 and 2. Approximately two years later, the Attorney General amended the complaint to charge "that the article claims of five patents owned by United States Gypsum were invalid and void." The defendants moved to strike the amendment on the ground that the government was estopped to attack the validity of the patents in the present proceedings, and that such attack would constitute a review of action by the Commissioner of Patents which was not authorized by statute. The lower court granted defendant's motion. The Supreme Court, specifically stating that, upon its view of the Sherman Act charges, it did not have to decide this issue (whether the government had the standing to challenge the validity of the patent) went out of its way to overrule the lower court. The Court stated at pp. 387–388:

> While this issue need not be decided to dispose of this case it seems inadvisable to leave the decision as a precedent. *Hurn* v. *Oursler*, 289 U.S. 238, 240. The United States does not claim that the patents are invalid because they have been employed in violation of the Sherman Act and that a decree should issue cancelling the patents; rather the government charges that the defendants have violated the Sherman Act because they granted licenses under patents which were in fact invalid. If the government were to succeed in showing that the patents were in fact invalid, such a finding would not in itself result in a judgment for the cancellation of the patents * * *.
>
> In an antitrust suit instituted by a licensee against his licensor, we have repeatedly held that the licensee may attack the validity of the patent under which he was licensed because of the public interest in free competition even though the licensee has agreed in his license not to do so [cases cited].
>
> In a suit to vindicate the public interest by enjoining violations of the Sherman Act the United States should have the same opportunity to show that the asserted shield of patentability does not exist. Of course this appeal must be considered on a record that assumes the validity of all the patents involved.

Recently the Supreme Court cited *U.S.* v. *U.S. Gypsum Co., et al.*,

333 U.S. 364 (1948), and had an opportunity to reiterate its concern with the standard of conduct before the Patent Office.[58]

In short, if the government may assert the *invalidity* of a patent in an antitrust suit, then this agency certainly can pass on the manner in which Pfizer procured its patent on tetracycline, "* * * and one need not resort to metaphysical subleties to denominate its conduct an unfair method of competition." (*Grand Union Co.* v. *F.T.C.*, 300 F. 2d 92, 99 (2d Cir., 1962).)

We are not holding that every misrepresentation of fact or withholding of material information before the Patent Office necessarily constitutes *per se* an unfair method of competition under the Federal Trade Commission Act. Some patents may be commercially worthless or have no adverse effects on competition. The facts of this case, however, are that a patentee has asserted monopoly rights under a patent so acquired and, as a consequence thereof, has restrained competition in the manufacture and sale of an important antibiotic; in at least one year the annual sales of tetracycline exceeded $100,000,000. The record further discloses that numerous drug houses have endeavored to enter the tetracycline market. All have been refused with the exception of respondents Cyanamid, Bristol, Squibb and Upjohn.[59]

XI

ALLEGED CONSPIRACY BEFORE THE PATENT OFFICE

Complaint counsel contend that the evidence of record sustains the charge that Cyanamid, Pfizer, and Bristol entered into an agreement or conspiracy to obtain a patent on tetracycline by fraud. The rec-

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[58] See *United States* v. *The Singer Manufacturing Company,* 31 U.S. L. Week 4674 (U.S. June 17, 1963).

Also of considerable interest on this point are the following comments:

"A recent report [S. Rep. No. 97, 82d Cong., 1st Sess. (1961)] by the Senate Subcommittee on Patents, Trademarks, and Copyrights noted that in sixty applications examined by it in which a final rejection was overcome by affidavits a 'substantial number' of the affidavits did not appear sufficient for that purpose. It thus appeared to the Subcommittee that the half-truths which had misled the examiners in those cases presented sufficient ground to seek methods which would, to some extent, remove the opportunity for fraud in the prosecution of patent applications." Cullen & Vickers, *Fraud In The Procurement of A Patent,* 49 G.W.L. Rev. 110 (1960).

[59] Soon after tetracycline was placed on the market, Pfizer made a public statement that it did not anticipate licensing others to manufacture tetracycline. (CX 1025, 1070 A–B) At least ten drug houses contacted several of the respondents, including Pfizer, in an attempt to buy it in bulk form for resale to the drug trade. (CX 336, 339, 341–43, 567–70, 571–74, 751–52, 1056–C) In 1954 Upjohn's President reported:

"Bristol tells us that most everyone in the industry has been after Bristol trying to get in on tetracycline."

(CX 942 H, 942 T) The closely-knit tetracycline industry should be compared with the penicillin market which was marked by many competing sellers and effective price competition. In 1948, for example, there were 42 firms competing in sales of penicillin. (RBX 950).

ord does show that each of these respondents withheld information from the Patent Office concerning inherent production of tetracycline with Aureomycin. There is no evidence, however, that Bristol did this by agreement or had knowledge that the others were withholding information or were intentionally making false statements.[60] As to Pfizer and Cyanamid, there are circumstances disclosed by the record which point to a possible conspiracy to suppress information concerning inherent production of tetracycline.[61]

Although these circumstances *standing alone* might constitute sufficient evidence to find that a conspiracy existed between Pfizer and Cyanamid, weighing all the evidence of record we do not find that complaint counsel has met the burden of proving this charge by substantial, reliable and probative evidence on the record as a whole. We wish to make it clear, however, that we are not finding that the evidence spells out an absence of a conspiracy, but merely that the evidence is inconclusive on this issue. The hearing examiner's conclusion that there was no conspiracy to defraud the Patent Office is based upon an erroneous finding that there was no withholding of information and no misrepresentation by any of the parties. We are in complete disagreement, therefore, with that part of the initial decision dealing with this subject and it is rejected.

XII

ALLEGED CONSPIRACY TO EXCLUDE OTHERS

We are also of the opinion that the evidence falls short of establishing an agreement among all five respondents to exclude competitors from the broad spectrum antibiotic market. Prior to the settlement of the tetracycline patent infringement suit an agreement would

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[60] Prior to the dissolution of the second interference Bristol and Squibb were conducting tests to determine whether tetracycline was coproduced with Aureomycin. Since a detective employed in October 1954 by Pfizer's general counsel was tapping the wires of these two concerns, it may be inferred that Pfizer and Bristol probably were not exchanging information on this subject.

[61] For instance, Cyanamid was aware of Lidoff's interest in inherent production when the exchange of proofs of priority with Pfizer took place during the first interference settlement in January 1954. Lidoff had previously rejected claims in two tetracycline applications (Minieri and Martin-Bohonos) on the ground of inherent production in Duggar and Niedercorn. Also, Edelblute on December 7, 1953, had filed a statement with Lidoff stating that Cyanamid had investigated samples of Aureomycin and had found no tetracycline and that the examiner "need, therefore, have no concern that the product tetracycline is not patentable." This statement was filed in the Boothe-Morton application which was the subject of the settlement negotiations. It would seem that the above information would have been of mutual concern to Pfizer and Cyanamid. Hutz and Edelblute (who respectively represented Pfizer and Cyanamid) deny, however, that they discussed these matters. Edelblute further testified that his December 7 statement was inadvertently omitted from the prosecution papers of the Boothe-Morton application submitted to Pfizer and that Pfizer therefore never saw this.

hardly have been consistent with the obvious efforts of Pfizer to exclude Bristol, Squibb and Upjohn. After this suit was settled each of the respondents undoubtedly realized that there would be no new entries in the tetracycline market. There is insufficient evidence, however, to prove that they expressly agreed among themselves to exclude others. The record shows, in this connection, that each of the respondents individually desired to exclude additional competitors in the sale of tetracycline. After the settlement of the aforementioned suit an agreement among them to foreclose market entry by other competitors was probably unnecessary.

At the time Cyanamid and Pfizer entered into cross-licensing agreements in January of 1954, these two firms accounted for over 90 percent of the total broad spectrum antibiotic sales with their patented products, Aureomycin and Terramycin. Chloromycetin, produced by Parke, Davis, was the only other broad spectrum antibiotic sold commercially prior to the introduction of tetracycline. For at least two years there had been no effective price competition in the marketing of these products and the prices of all three had remained stable and uniform. By the fall of 1953, both Cyanamid and Pfizer realized that the therapeutic utility of tetracycline was at least equal to that of the other broad spectrums and that tetracycline, if produced and sold commercially, would be fully competitive with Aureomycin and Terramycin. Both firms had good reason to believe that the dominant positions they enjoyed in the broad spectrum field would be seriously impaired by unrestricted competition in the production and sale of the antibiotic tetracycline. The entry of new firms could lead to price cutting and a downward trend in the prices of all broad spectrum antibiotics could be expected.

Both Cyanamid and Pfizer had filed applications for a patent on tetracycline and the deschlorination process for its manufacture. Each firm had reason to believe that the other had filed such an application but, prior to the announcement by Heyden Chemical Corporation on September 25, 1953, that it had produced tetracycline by fermentation and had filed a product and process patent application, neither was aware that some other firm was in the tetracycline race. Cyanamid promptly acquired Heyden's Antibiotic Division. There is no evidence that this acquisition by Cyanamid was made as the result of an understanding or agreement with Pfizer as contended by complaint counsel.[62]

After the Heyden acquisition, Cyanamid and Pfizer learned that Bristol had also filed an application for a patent on tetracycline and a fermentation process for its production. They also became aware

[62] See Findings, Paragraph 9.

that Bristol definitely intended to obtain a share of the tetracycline market and that Bristol would sell tetracycline in bulk to other manufacturers.

The record shows, contrary to the hearing examiner's findings, that Cyanamid did not believe that the production and sale of tetracycline could be controlled by the Duggar and Niedercorn patents but, having entered into a cross-licensing agreement with Pfizer, wanted a patent on this product to be obtained by Pfizer. In this connection, Cyanamid had reason to believe that tetracycline product claims in the various patent applications would be rejected by the patent examiner handling the applications on the ground that tetracycline had been inherently produced in the Duggar and Niedercorn processes. The patent examiner had already rejected the fermentation process claims in the Minieri application on the assumption that tetracycline was coproduced in Duggar and Niedercorn [63] and had informed Cyanamid's patent attorney that he considered inherent production as adequate grounds for rejecting product claims. The record shows that the Cyanamid scientists discovered by December of 1953, prior to the date of the cross-licensing agreements, that coproduction of tetracycline did occur in the manufacture of commercial Aureomycin. Instead of taking the position before the Patent Office that tetracycline was unpatentable, Cyanamid entered into the cross-licensing agreement with Pfizer, again denied that tetracycline was coproduced with Aureomycin, and withheld information indicating that such coproduction occurred. Cyanamid's cooperation with Pfizer during the second interference before the Patent Office further demonstrates that Cyanamid did not believe that it could control the production and sale of tetracycline by means of its Aureomycin patents. The hearing examiner has inconsistently held in this connection that Cyanamid knew that it unilaterally possessed the power to exclude other manufacturers of tetracycline but that Cyanamid's cooperation with Pfizer during the second interference was "logical" because Cyanamid lacked this power. (Initial Decision, pp. 26, 36) [64]

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[63] Malcolm, President of Cyanamid, testified that he was aware of this rejection and had discussed it with Cyanamid's patent attorney. He later changed his testimony and claimed that he had no knowledge whatsoever of this rejection or the reason therefor. (Tr. 5477, 5486)

[64] Malcolm testified that he was "extremely happy" when he learned that the patent examiner had rejected all product claims because he then knew that Cyanamid would be able to control tetracycline under its Duggar patent. However, Cyanamid's patent attorney, Edelblute, who worked closely with Malcolm, stated with respect to the patent examiner's ruling, "This is, of course, a very unexpected and disturbing outcome of the interference" * * *. (RACX 878) He also informed Malcolm, at the time that he had requested Cyanamid's laboratories to make investigations which would help Pfizer overcome the assumption of inherent production upon which the patent examiner based his ruling. Another Cyanamid official wrote, at the time, that he hoped the news of the rejection of the tetracycline claims would not spoil Malcolm's vacation. (RACX 879)