
IN THE MATTER OF
AMERICAN CYANAMID COMPANY ET AL.
ORDER, OPINIONS, ETC., IN REGARD TO THE ALLEGED VIOLATION OF
THE FEDERAL TRADE COMMISSION ACT

Docket 7211. Complaint, July 28, 1958—Decision, Sept. 29, 1967

Order modifying an earlier Commission order dated Dec. 17, 1963, 63 F.T.C. 1747, after a rehearing on remand from the U.S. Court of Appeals for the Sixth Circuit, 363 F. 2d 757(8 S.&D. 248), by requiring two manu-

Initial Decision

72 F.T.C.

facturing chemical firms to grant to any domestic applicant nonexclusive licenses to make and sell two of their patented antibiotics and furnish such licensees certain technical information.

Mr. Ernest G. Barnes, Mr. Herbert Karzen, and Mr. Daniel H. Hanscom supporting the complaint.

Donovan, Leisure, Newton and Irvine, New York, N.Y., by Mr. Richard Y. Holcomb and Mr. Kenneth Hart for respondent American Cyanamid Company.

Winthrop, Stimson, Putnam and Roberts, New York, N.Y., by Mr. Merrell E. Clark, and Mr. Henry J. Zafian for respondents Bristol-Myers Company and Bristol Laboratories, Inc.

Dewey, Ballantine, Bushby, Palmer and Wood, New York, N.Y., by Mr. John E. F. Wood and Connolly, Bove & Lodge, Wilmington, Del., by Mr. Arthur G. Connolly for respondent Chas. Pfizer & Co., Inc.

Cravath, Swaine and Moore, New York, N.Y., by Mr. Allen F. Maulsby and Mr. John F. Bradley for respondent Olin Mathieson Chemical Corporation.

Covington & Burling, Washington, D.C., by Mr. Nestor S. Foley and Mr. Gerhard A. Gesell for respondent The Upjohn Company.

INITIAL DECISION ON REMAND BY ABNER E. LIPSCOMB, HEARING EXAMINER

NOVEMBER 9, 1966

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I. HISTORY FROM COMPLAINT TO HEARING ON REMAND

A. *The Complaint*

The complaint in this proceeding, issued on July 28, 1958, charges the respondents named therein with the use of unfair methods of competition and unfair and deceptive acts and practices in commerce in the sale of *tetracycline*, an antibiotic, in violation of the provisions of Section 5 of the Federal Trade Commission Act.

In addition to various other factual charges, the complaint specifically charges all respondents with fixing and maintaining an arbitrary and rigid price for tetracycline through conspiracy and combination.

The complaint describes the antibiotic industry as one of dynamic growth with sales exceeding \$330 million per year and with tetracycline enjoying the largest sale by dollar volume, aggregating more than \$100 million in 1957.

The major factual charge of the complaint, however, and the only major charge with which we are concerned in this initial

decision or remand, is the charge that Chas. Pfizer & Co., Inc. (hereinafter referred to as Pfizer) and American Cyanamid Company (hereinafter referred to as Cyanamid) made false, misleading, and incorrect statements to, and withheld material information from, the United States Patent Office with the purpose and effect of inducing or causing the issuance of a patent on the antibiotic tetracycline to Pfizer.

B. Hearings and the Initial Decision

After extended hearings, which resulted in over 11,000 pages of transcript and numerous exhibits, Robert L. Piper, the hearing examiner in this original proceeding, filed his initial decision on October 31, 1961, in which he held that the charges of the complaint had not been sustained by the evidence. Accordingly, he ordered that the complaint be dismissed.

C. The Commission's Decision of August 8, 1963

On August 8, 1963, the Commission, after considering the appeal of counsel supporting the complaint from Mr. Piper's initial decision and the entire record of this proceeding, vacated and set aside that initial decision, made its own findings as to the facts and conclusions drawn therefrom, and issued its own order, requiring the respondents to cease and desist from those acts and practices that the Commission found to be illegal, including a prohibition concerning the major charge of wrongfully inducing the United States Patent Office to issue a patent for tetracycline to Pfizer.

D. The Remand to the Commission by the United States Court of Appeals for the Sixth Circuit

Respondents appealed to the United States Court of Appeals for the Sixth Circuit from the Commission's decision of August 8, 1963, and its Final Order thereon, dated December 17, 1963 [63 F.T.C. 1747]. On June 16, 1966 [8 S.&D. 248], the Court vacated that order and remanded this entire case to the Commission for the purpose of "a *de novo* hearing on all issues without the participation of Chairman Dixon." The Court of Appeals held that Chairman Dixon was disqualified to participate in the Commission's decision because of his previous service as Chief Counsel and Staff Director of the Subcommittee on Antitrust and Monopoly of the Committee of the Judiciary of the United States Senate. This Committee had investigated many of the same facts involved in the present proceeding. The Court further ruled that the Commission's findings that material misrepresentations had been

made to the United States Patent Office and that material information had been withheld from it by Cyanamid and Pfizer, was not supported by substantial evidence. The Court suggested that additional evidence should be secured from Patent Examiner Herbert J. Lidoff, who had not testified during the original hearings, in order to determine if he, the patent examiner who approved the granting of a patent for tetracycline, had been misled or deceived by Pfizer and Cyanamid. The Court also suggested that any other witnesses who had testified relevant to the procuring of the patent should be allowed to testify to the facts relating thereto. In addition, the Court suggested a number of very pertinent questions that Mr. Lidoff should be asked if he were called to testify herein. (*American Cyanamid Co. et al. v. F.T.C.*, 363 F. 2d 757 (6th Cir. 1966).)

E. The Remand to the "Chief Hearing Examiner"

After the Court remanded this proceeding to the Commission, the Commission, by order dated August 1, 1966 [70 F.T.C. 1763], reopened this proceeding and remanded it to the "Chief Hearing Examiner for assignment to an examiner to begin expeditious hearings." Since Robert L. Piper, the hearing examiner who originally heard this case and wrote the initial decision herein, was no longer in the employ of the Commission, the remanded proceeding was assigned to the present presiding hearing examiner for the limited purpose stated in the Commission's order.

II. THE ISSUES ON REMAND

The Commission in its remand order specified that a hearing was to be held for:

the sole and limited purpose of receiving the testimony of Patent Examiner H. J. Lidoff, and of any other witnesses who have heretofore testified, with respect to "the issue as to whether Pfizer and Cyanamid made misrepresentations to the Patent Office and withheld essential information, thereby deceiving Lidoff into granting a patent which otherwise never would have been approved."

The Commission's order further specified that the hearing examiner should submit an initial decision "confined to the issue hereinabove specified."

III. THE HEARING ON REMAND

In compliance with the Commission's order of remand, a hearing was held in Washington, D.C., on September 12 and 13, 1966, at which Patent Examiner Herbert J. Lidoff was presented as a

witness by counsel supporting the complaint, and Werner Hutz, an attorney, and Dr. Francis X. Murphy, a scientist, were presented as witnesses by Pfizer.

IV. FACTS IN THE ORIGINAL RECORD NECESSARY TO THE ISSUES ON REMAND

Before evaluating the testimony of the witnesses who testified on the remand of this case and before making factual findings based on their testimony and on such additional evidence from the original record as relates thereto, it seems necessary to a coordinated presentation of the issues on remand to present first, a summarization of the antibiotic industry; second, a brief explanation of antibiotics; and third, the proceeding before the United States Patent Office that led to the issuance of the patent for tetracycline.

A. *The Antibiotics Industry*

(The following discussion is quoted from the opinion of the United States Court of Appeals for the Sixth Circuit in *American Cyanamid Co., et al. v. F.T.C.*, *supra*, pp. 760-61 [8 S.&D. 248, 252-253].)

Tetracycline, a broad-spectrum antibiotic, is sold and distributed under various trade names by all five petitioners: Chas. Pfizer & Co., Inc. ("Pfizer"), American Cyanamid Company ("Cyanamid"), Bristol-Myers Company and Bristol Laboratories ("Bristol"), Olin Mathieson Chemical Corporation through its E. R. Squibb & Sons Division ("Squibb") and the Upjohn Company ("Upjohn"). Pfizer owns the patent on tetracycline and produces it in addition to selling and distributing.

Under licenses granted by Pfizer, Cyanamid and Bristol also produce this antibiotic as well as selling and distributing it. Squibb and Upjohn sell and distribute by authority of licenses granted by Pfizer.

Also involved are two older antibiotics: (1) chlortetracycline, which is produced and sold by Cyanamid, owner of its patents, as aureomycin; and (2) oxtetracycline, which is produced and sold by Pfizer, owner of its patent, as terramycin.

Antibiotics are chemical substances produced by certain microorganisms. They have the capacity to counteract and cure a broad variety of diseases. At the end of World War II, penicillin was the principal antibiotic. It was a "narrow-spectrum" drug with more limited effectiveness than the "broad-spectrum" antibiotics. Penicillin was not patented. Its production and sale proved to be fiercely competitive and profits were marginal.

The antibiotics involved in this case were described by the Commission as follows:

"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. 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 prescription. 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."

B. *Proceedings Before Patent Office*

(The following discussion is quoted from the opinion of the United States Court of Appeals for the Sixth Circuit in *American Cyanamid Co., et al. v. F.T.C.*, *supra*, pp. 761, 773-75 [8 S.&D. 248, 253-254, 269-272].)

When Cyanamid obtained a patent on aureomycin in 1949, the molecular structure of that drug was not known. The patent application described it in terms of certain secondary chemical properties. In 1952 the molecular structure was discovered, and a Pfizer scientist speculated that an antibiotic of at least equal strength could be produced by altering only slightly the structure of aureomycin. The result was a vastly improved antibiotic, tetracycline, which first was produced by Pfizer scientists in 1952.

Within six months of the discovery of tetracycline, both Pfizer and Cyanamid filed applications for patents. (Pfizer's application is described in the record as the "Conover application" and Cyanamid's as the "Boothe-Morton application.") The Patent Office declared an interference, which was settled as a result of a private cross-licensing agreement between Pfizer and Cyanamid to the effect that the party found to have priority would license the other. Thereafter Cyanamid conceded priority to Pfizer and withdrew its application.

Bristol then filed a patent application. A second interference was declared. The patent examiner filed an opinion which concluded that tetracycline was unpatentable. Pfizer thereupon submitted affidavits to the effect that tetracycline could not be recovered from broths representative of those described in the Cyanamid patent application on aureomycin. Shortly afterwards a product patent was issued to Pfizer.

* * * * *

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.

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 patent 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 six per cent aureomycin in the production of tetracycline, and to sell tetracycline containing not more than six per cent 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.

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 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.

On September 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 November 4, 1953, Cyanamid purchased Heyden's antibiotic facilities, including the rights to the Minieri tetracycline patent application.

H. J. Lidoff, the patent examiner handling the Cyanamid and Pfizer patent applications, declared 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.

The first interference was terminated on February 9, 1954, following the execution of the cross-licensing agreement between Pfizer and Cyanamid. Cyanamid conceded that the Pfizer (Conover) application had priority in time and withdrew its Boothe-Morton application.

On January 15, 1954, Bristol had filed continuation applications in the Heine-mann matter, claiming tetracycline hydrochloride, and contending that this product was patently distinguishable from tetracycline.

On March 2, 1954, Examiner Lidoff declared a second interference. The parties to this interference were Pfizer (Conover application), Bristol (Heine-mann application) and Cyanamid (Minieri application which it had purchased from Heyden).

On October 14, 1954, Examiner Lidoff dissolved the second interference, ruling that the product tetracycline was not patentable, and rejected all product claims on the basis of coproduction, i.e. that the previously patented aureomycin process (Duggar and Niedercorn patents) inherently produced certain amounts of tetracycline. The Minieri application filed by Heyden on September 25, 1953, had disclosed that the microorganisms 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. He also held that tetracycline hydrochloride was not patently distinguishable from tetracycline.

On November 29, 1954, Pfizer's patent representatives met with Examiner Lidoff in his office concerning the rejection of the Conover application on the

ground of the unpatentability of tetracycline because of inherent production. The statements made at this interview and the affidavits and statements made concerning experiments conducted as a result of this interview encompass most of the misrepresentations which the Commission found Pfizer to have made in its successful effort to persuade Examiner Lidoff to change his decision.

V. RULINGS ON PROPOSED FINDINGS AS TO THE FACTS

Opposing counsel submitted proposed findings as to the facts, proposed conclusions, proposed orders, briefs in support thereof, and reply briefs. All proposals have been considered by the hearing examiner, and those not incorporated herein, either verbatim or in substance, are hereby rejected.

VI. EVALUATION OF THE TESTIMONY OF PATENT EXAMINER HERBERT J. LIDOFF

Herbert J. Lidoff, who testified at the hearings of this proceeding on September 12 and 13, 1966, identified himself as presently a member of the Board of Appeals of the United States Patent Office; as having been employed by that agency since May 1937; and as having been an assistant patent examiner at the time he handled the patent application of Pfizer in 1954.

In his testimony Mr. Lidoff frankly admitted that he did not remember the details of his various interviews with Werner Hutz and Dr. Francis X. Murphy, who represented Pfizer in procuring the patent on tetracycline. Mr. Lidoff testified in substance, however, that, based on the policies and practices of his agency, on his own convictions concerning the issuance of patents, and on what he would have done under certain given circumstances, he could reconstruct his views and reactions to the various questions directed to him about the interviews and actions taken by him in 1954.

Counsel for respondents Pfizer and Cyanamid contend that, as a result of Mr. Lidoff's frank admissions concerning his failure to remember the details of interviews occurring in 1954, his reconstructed testimony concerning those interviews and his reaction to questions concerning them adds nothing to the strength of the record as it was before this remand and as it was at the time it was reviewed by the United States Court of Appeals for the Sixth Circuit. They contend further that the testimony in the record, as supplemented by Mr. Lidoff's testimony, does not constitute substantial evidence showing misconduct on the part of respondents Pfizer and Cyanamid and, accordingly, that the complaint herein should be dismissed. We do not agree with counsel's contention.

The record shows no incentive for Mr. Lidoff to distort the truth. On the contrary, we believe that there is a normal, human tendency to justify one's previous conduct, and it would have been easier, therefore, for Mr. Lidoff to have testified so as to justify the issuance of the patent in question rather than to repudiate his own prior act. Moreover, it has been our observation that the witness who remembers too well and too clearly may be less credible than the witness who has difficulty in remembering. We believe that the testimony of Werner Hutz and Dr. Francis X. Murphy does not substantially detract from the force of Mr. Lidoff's testimony. Mr. Lidoff's testimony, which was presented clearly and unequivocally, explains the numerous factual problems that confronted both the Commission and the Court in their evaluations of the original record; and it supplements and explains clearly proven facts in the record. Those facts, combined with Mr. Lidoff's testimony, present clear, convincing, and substantial evidence to support and sustain the facts herein found.

VII. FINDINGS AS TO THE FACTS ON THE ISSUES ON REMAND

A. *Rejection of Respondents' Applications on October 14, 1954*

The United States Patent Office rejected respondents' applications to patent tetracycline on October 14, 1954, on the speculation that identifiable tetracycline had been and was produced under the Duggar and Niedercorn Aureomycin patents.

The above finding is required by the evidence shown in the Court's opinion cited at end of the preceding section; by CX 12, pp. 443-44; and by the testimony of Mr. Lidoff (Tr. 11501).

B. *Rejection of Pfizer's Application on November 24, 1954*

The United States Patent Office, on November 24, 1954, rejected Pfizer's application to patent tetracycline for the same reason it had rejected respondents' applications on October 14, 1954; that is, because of the speculation by Mr. Lidoff that the Duggar and Niedercorn patents on Aureomycin had disclosed the presence of tetracycline (CX 4, pp. 31-32).

Patent Examiner Lidoff testified that, according to the patent statutes, a chemical compound is not patentable if it is not novel (Tr. 11496). He therefore rejected the product claims of the Pfizer "Conover" patent application on November 24, 1954, on the ground that tetracycline was not novel because, as he speculated from the Cyanamid "Minieri" patent application, tetracycline appeared to be coproduced in the production of Aureomycin (Tr. 11496-97).

Because the "Minieri" application was available to Pfizer during the second interference proceeding, Patent Examiner Lidoff was able to base his speculation on the disclosures of that application (Tr. 11496). He was of the opinion that, if the compound tetracycline could be identified in the broths of the prior Duggar and Niedercorn patents, it was not "new" and a patent could not validly be issued (Tr. 11496-97, 11500, 11531, 11579, 11580, 11601).

In connection with the rejection of Pfizer's application, the patent examiner testified that the proportion, percentage, or amount of the prior production of tetracycline was not significant—"The presence was the important thing." (Tr. 11497; see also Tr. 11505, 11526, 11527, 11528-29, 11563, 11579.) In fact, the presence of identifiable tetracycline in the fermentation broths produced pursuant to the prior Duggar and Niedercorn patents "* * * was the crux of the whole issue." (Tr. 11500; see also 11563, 11568.) Further, Patent Examiner Lidoff made it clear that it was not necessary for a therapeutic product to be coproduced (Tr. 11530, 11545A), or for sufficient tetracycline to be present to give tetracycline activity to the mixture (Tr. 11589, 11590), or for commercial amounts of tetracycline to be coproduced (Tr. 11526, 11579, 11725). It was only necessary that there be sufficient tetracycline to be identified (Tr. 11589).

C. Pfizer's Representatives Deny the Basis for Rejection of Its Application on November 29, 1954

On November 29, 1954, following the rejection of its application for a patent on tetracycline on November 24, 1954, Pfizer's patent representatives Werner Hutz and Dr. Murphy visited Mr. Lidoff at the Patent Office and vigorously denied the speculative basis on which Mr. Lidoff had rejected Pfizer's application (Tr. 11502). As a result of this denial of inherent coproduction of tetracycline in the Duggar and Niedercorn broths, an issue of fact arose. In the Patent Office the normal method for resolving such an issue of fact is by affidavits produced by the patent applicant, since the Patent Office has no facilities for conducting tests (Tr. 11503). The patent examiner was of the view that if identifiable tetracycline were present in the Duggar and Niedercorn patent fermentation broths, tetracycline would not be novel and no valid patent could be issued (Tr. 11500). The factual question that the patent examiner was attempting to get answered, therefore, was whether identifiable tetracycline was, or was not, present in the broths of the referenced patents (Tr. 11506, 11531, 11545A, 11568).

D. *Herbert J. Lidoff Did Not Know of Presence of Identifiable Tetracycline in Aureomycin*

As of December 9, 1954, the date on which the Notice of Allowance of the patent on "tetracycline" was issued to Pfizer (CX 4, p. 64), and prior thereto, the patent examiner did not know as a fact that any identifiable tetracycline was inherently produced in the Duggar and Niedercorn patent fermentations (Tr. 11507), and the patent examiner so testified. Further, his rejection on November 24, 1954, of Pfizer's claim to tetracycline in the Conover patent and his Order of October 14, 1954, dissolving the second interference proceeding, show clearly that they were based on a speculation. Mr. Lidoff had no definite facts to establish that tetracycline was produced in the prior Duggar and Niedercorn patent fermentations (CX 4, pp. 31-32; CX 12, pp. 443-44; Lidoff, Tr. 11496-97, 11501, 11586). Information that Duggar and Niedercorn did in truth produce recognizable tetracycline would have been sufficient to have prevented the issuance of a patent on tetracycline.

As stated, the rejection of the Pfizer application for a patent on tetracycline was based on a speculation that published patents, the Duggar and Niedercorn patents, produced some tetracycline (Tr. 11496-97, 11500, 11501, 11505). Information that commercial Aureomycin contained any identifiable tetracycline would have raised a somewhat different issue of patentability and would have effectively barred a patent on tetracycline under a different portion of the patent statutes (Tr. 11505, 11519-20, 11528, 11534).

As of December 9, 1954, the date on which the Notice of Allowance of the Conover patent was issued to Pfizer (CX 4, p. 64), and prior thereto, the patent examiner did not know as a fact that commercial Aureomycin contained tetracycline (Tr. 11507, 11533). Information that publicly available commercial Aureomycin did contain tetracycline would have caused the rejection of Pfizer's claim to tetracycline in the Conover patent application (Tr. 11519) and would have prevented the issuance of the Conover patent to Pfizer (Tr. 11505, 11519-20).

E. *Pfizer's Scientists Knew in 1953-54 that Tetracycline Could Be Identified in Aureomycin*

Pfizer's scientists knew from the experimental tests conducted within their organization that tetracycline could be identified, separated, or recovered from the Duggar and Niedercorn Aureomycin fermentation and from the product Aureomycin.

Pfizer's scientists, during 1953 and 1954, worked on the development of methods to produce tetracycline by direct fermentation

(CX 51A and B; Dr. Grove, Tr. 2821-29). Sometime prior to October 9, 1953, a leading Pfizer scientist subjected a 250 mg. capsule of commercial Aureomycin to a Craig countercurrent separation procedure and found tetracycline therein (CX 37, p. 88; Grove, Tr. 2835-56; CX 35, p. 259; CX 37, pp. 86-92). Dr. Bogert, the Pfizer scientist who conducted the recovery tests, testified that he knew, prior to the time he conducted the tests, that Aureomycin contained tetracycline (CX 37, pp. 24, 30). Pfizer's scientists also found that some strains of *S. aureofaciens* produced tetracycline. Therefore, on November 12, 1953, Dr. Tanner and other of Pfizer's scientists filed a patent application for a process that made tetracycline by direct fermentation (CX 921, CX 50, 51A and B, CX 33, pp. 164-5; Tanner, Tr. 3988-92).

On October 15, 1954, one day after the dissolution of the second interference, Dr. Murphy, a former Pfizer research chemist, who was then employed by Pfizer as a patent agent (Murphy, Tr. 11673, 11711-12; CX 35, p. 3), issued memoranda to two of Pfizer's scientists, Dr. Tanner and Dr. Bogert (the two scientists who later actually conducted the tests reported to the Patent Office through affidavits), instructing them to conduct work on the coproduction of tetracycline in the Duggar and Niedercorn patent fermentations (CX 55, 57, and CX 33, pp. 170-73). In these memoranda he directed them to use the strain of *S. aureofaciens*, NRRL-2209, that had been deposited by Cyanamid in the public culture collection of the Northern Regional Research Laboratory maintained by the Federal Government.

Dr. Murphy made it clear to these scientists that the work was in connection with the prosecution of the Pfizer Conover application to patent tetracycline and that the results might be used in preparing affidavits for the Patent Office (CX 55, 57). In particular, Dr. Tanner was instructed to summarize all fermentation work that had been conducted to date with the publicly available strain of *S. aureofaciens*:

* * * particularly with respect to the proportion of Aureomycin and tetracycline produced on media specifically described or generally disclosed in the Duggar and Niedercorn Aureomycin patents. (CX 55.)

Dr. Tanner was further instructed to conduct actual 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 and the Aureomycin and tetracycline content (CX 55).

Dr. Bogert, in turn, was instructed to recover and to purify by the "Pidacks Florisil-column" procedure (a method of recovery

referred to in the Duggar patent) those antibiotics present in the fermentation broths prepared by Dr. Tanner and to determine their total broad spectrum potency (CX 57). And, Dr. Bogert was specifically instructed to submit his results for determination of the Aureomycin and the tetracycline content of the recovered products to Dr. Murphy (CX 57). In connection with the latter instruction, Dr. Murphy stated:

This [tetracycline content] presumably will be determined primarily by paper chromatography. However, if other methods are available for determination of this ratio, these should also be utilized. (CX 57.)

The "Pidacks Florisil-column" procedure—a column chromatographic procedure disclosed in the Duggar patent as a method of separating or 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 through it. This 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. Langlykke, Squibb's Director of Research and Development, Tr. 9908, 10038-9; Dr. Stodola, Tr. 2016-7).

Dr. Bogert, in a test run on a Niedercorn broth in November 1954, determined that almost all of the tetracycline present is destroyed when one strictly follows the Pidacks Florisil-column procedure but the result could be obviated by a slight modification of the procedure (CX 59, 60; Bogert, Tr. 4413; CX 58C; see also Bogert, Tr. 4270-71, 4464-65; CX 37, p. 30).

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 then removed from the solvent, immobilizing spots of the material that have migrated. Tests have established that tetracycline and other products have certain characteristics as to the rate at which they migrate. 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. Paper chromatography can be used to determine the percentages of the tetracycline present by measuring the zone of inhibition of the bacteria test organism present in the agar medium (Grove, Tr. 2830-32; Bogert, Tr. 4433-34; Stodola, Tr. 2017; Woodward, Tr. 4586-92, a Pfizer witness in this proceeding, was a Professor of Chemistry at Harvard University,

Tr. 4530; Dr. Woodward was recently awarded the Nobel Prize, Tr. 11560).

The Craig countercurrent separation procedure is a method that can be used to recover tetracycline in a mixture with Aureomycin (Bogert, Tr. 4434; Dr. Grove, Tr. 2835-37; Woodward, Tr. 4592-4600, 4586; Dr. Waksman, Tr. 7367-69, 7385, 7435-6; Dr. Taylor, Tr. 9263-4, 9353-4; CX 141A-Z19; CX 1069B, G, O-T; CX 133A-C; CX 168; CX 1037; CX 92A-B; CX 99B; CX 123C, E, F; CX 912; CX 9, p. 79; CX 1099A-C; CX 1062, p. 29; CX 38, pp. 3-4). It is based on the manner in which a substance will distribute itself between two immiscible solvents. Two substances that have different distribution coefficients, such as tetracycline and Aureomycin, can be separated by this method and the tetracycline can be recovered (Dr. Grove, Tr. 2835-7; Dr. Woodward, Tr. 4592-4600).

Pursuant to the instructions given by Dr. Murphy, Dr. Tanner prepared several patented broths, among them were two broths prepared in accordance with the specifications set forth in Niedercorn Example 1. Significantly, one of these broths had a bio-assay potency of 75 micrograms per milliliter (CX 56A, CX 33, p. 178; Dr. Grove, Tr. 2828-29). Dr. Bogert applied a modified Pidacks Florisil-column recovery procedure to this broth and obtained a number of fractions that were found by paper chromatography to contain tetracycline (CX 58C; Bogert, Tr. 4408-11). These findings were recorded as:

Fract.	Paper	Chromatography
4	5%	tetracycline
5	5%	"
6	5%	"
7	5%	"
8	10%	"
9	8%	" (CX 58C.)

Dr. Bogert testified that these tests showed tetracycline to be present, and to be present in quantities of about "five percent" (CX 37, p. 30; Bogert, Tr. 4412).

Expert testimony in this proceeding establishes that tetracycline could have been recovered from these fractions as early as October 1954 (Dr. Grove, Tr. 2826; Dr. Stodola, Tr. 11032, 11043-45).

F. Disclosure of Identified Tetracycline in Duggar or Niedercorn Broths Would Have Confirmed Lidoff's Speculation

If Pfizer's representatives, on November 29, 1954, had disclosed that Pfizer's scientists had identified tetracycline in the Duggar

and Niedercorn fermentation broths, the patent examiner's speculation that tetracycline was present in those broths would have been correct, tetracycline would have been unpatentable, and no further test would have been specified.

Patent Examiner Lidoff testified that Pfizer's representatives vigorously denied at their conference with him on November 29, 1954, that tetracycline was also produced in the Duggar and Niedercorn Aureomycin fermentations. Mr. Lidoff testified (Tr. 11502) :

Q. Did they [Pfizer's representatives] deny your speculative basis for the co-production of tetracycline in the Duggar-Niedercorn patent fermentation broths?

A. Vigorously.

Patent Examiner Lidoff further testified that if Pfizer's representatives had informed him at the conference on November 29, 1954, that Pfizer's scientists had recently prepared a fermentation broth pursuant to Example 1 of the Niedercorn patent and found fractions thereof to contain between 5 percent and 10 percent tetracycline, this information would not only have been material to his consideration of Pfizer's claim to patent tetracycline, but this would have ended the matter (Lidoff, Tr. 11504).

Patent Examiner Lidoff testified that this information would have been: "Not only material, but determinative of non-patentability of the claims then before me" (Tr. 11504).

G. Pfizer's Failure to Disclose Information Causes Patent Examiner to Consent to Special Tests

The failure of Pfizer's representatives to disclose facts in the possession of its scientific staff that showed identifiable tetracycline was produced under the Duggar and Niedercorn patents caused Patent Examiner Lidoff to consent to special tests to resolve the issue between himself and these representatives.

At the November 29, 1954, conference Pfizer's representatives denied that tetracycline was coproduced under the Duggar and Niedercorn patents; however, Mr. Lidoff adhered to the speculative basis for his rejection. Therefore, it was agreed that Pfizer, in accordance with Patent Office practice, would conduct tests to determine if tetracycline was also produced in the Duggar and Niedercorn patent fermentations, and thus "resolve" the outstanding issue of fact presented by the patent examiner's speculation that tetracycline was unpatentable (Lidoff, Tr. 11502-03).

These tests came about only because of Pfizer's denial of coproduction. If Pfizer had admitted coproduction at the November

29th interview, this would have been determinative of nonpatentability (Lidoff, Tr. 11504). The Patent Office cannot require that tests be made, but an applicant may, if he desires, present data in affidavit form (Lidoff, Tr. 11529). It is not the function of the patent examiner to require tests or to point out specifically the tests to be made (Lidoff, Tr. 11529).

In presenting affidavit information to the Patent Office, Pfizer was not limited in the tests to be performed, or the procedures to be utilized (Lidoff, Tr. 11510, 11530, 11610-11); Pfizer was not limited to repeating Niedercorn Example 28 (Lidoff, Tr. 11530, 11610-11); and Pfizer was not limited to the use of the three recovery procedures actually used in conducting the tests (Lidoff, Tr. 11545A, 11572, 11583, 11725).

The patent examiner was trying to find out from Pfizer whether or not any identifiable tetracycline was produced in the prior Duggar and Niedercorn fermentation broths (Lidoff, Tr. 11506). He expected Pfizer's representatives to answer this question and to use the patent examples most likely to produce tetracycline (Lidoff, Tr. 11609-10). He also expected them to utilize the most sensitive or delicate tests available in an attempt to identify any tetracycline present in the broths (Lidoff, Tr. 11572, 11609-10). In other words, Patent Examiner Lidoff desired to obtain the best evidence available on this point (Tr. 11506, 11511, 11583, 11609-10).

H. Pfizer's Failure to Disclose That Example 28 Had Little or No Antibiotic Potency Led to Its Use in Test

The failure of Pfizer's representatives to disclose to Patent Examiner Lidoff on November 29, 1954, that earlier testing work had revealed little or no antibiotic potency was obtained from Niedercorn Example 28 led to the acceptance of that example for the test agreed upon.

At the November 29, 1954, conference with the patent examiner, Pfizer's representatives did not, as already described, disclose that Dr. Bogert had previously found the publicly available culture of *S. aureofaciens*, NRRL-2209, when fermented in the medium described in Example 1 of the Niedercorn patent, would produce a broth of 75 micrograms per milliliter potency. Nor did they disclose that by using a modified Pidacks Florisil-column procedure and paper chromatography Dr. Bogert found approximately 5 to 10 percent of the antibiotic produced to consist of tetracycline (CX 58C; Lidoff, Tr. 11504; CX 4, pp. 34-40). Furthermore, Pfizer did not disclose that Dr. Tanner, in September and October of 1954, as part of a general research project to

determine the production of tetracycline by various means of fermentation, had fermented *S. aureofaciens*, NRRL-2209, in a Niedercorn patent Example 28 medium and had found the resulting broths to be less than 10 micrograms per milliliter (CX 33, pp. 179-180). These broths were so poor in antibiotic potency that Dr. Tanner had classified them as containing no Aureomycin or tetracycline (CX 1018B; Tanner, Tr. 4127-30). The Niedercorn Example 28 specifies that a potency of 274 micrograms per milliliter should be obtained when following that Example. Dr. Tanner's work, which was crucially relevant to a determination as to the appropriateness of Pfizer's affidavit tests, was not disclosed to Mr. Lidoff (Lidoff, Tr. 11508-9; CX 4, pp. 34-40).

I. Pfizer Misrepresented Its Test's Fermentation as Truly Representative

After the interview of November 29, Dr. Murphy immediately notified Drs. Tanner and Bogert that tests were to be conducted for the Patent Office to determine whether tetracycline could be obtained from a Duggar broth and a Niedercorn Example 28 broth using the three recovery procedures described in the Bogert-Walsh, Minieri, and Heinemann patent applications. Dr. Tanner prepared two broths—one allegedly a duplication of the Duggar patent and one allegedly representative of Niedercorn patent Example 28. These broths were designated 1771A and 1771B (CX 61). At the request of Dr. Bogert, both biological and chemical assays were made of these broths by other of Pfizer's scientists. The potency, *i.e.* antibiotic content, of 1771A was assayed at only 6.9 micrograms per milliliter by biological assay and 8.3 by chemical assay (CX 62A; CX 37, p. 74). The potency of 1771B was assayed at only 5.2 micrograms per milliliter by biological assay and 14.3 by chemical assay (CX 62F; CX 37, p. 74). The record establishes that for low potency broths, the biological assays are more accurate (CX 37, p. 74; Tanner, Tr. 4290; Dr. Grove, Tr. 2870-71; Tanner, Tr. 4059, 4062; Murphy, Tr. 11695).

Notwithstanding the low potency of the Niedercorn test broth, Pfizer's representatives misleadingly told the patent examiner that this broth was "truly representative" of a Niedercorn Example 28 broth (CX 4, p. 38, lines 2 and 19). The actual potency figures were not revealed to Patent Examiner Lidoff (CX 37, pp. 113-14), and expert testimony in the proceeding establishes that the potencies of the test broths cannot be calculated from the data contained in the Pfizer affidavits (Dr. Stodola, Tr. 1912; Dr. Johnson, Tr. 2400; Dr. Grove, Tr. 2868-69; Dr. Stodola, Tr.

1982-85). The record also clearly establishes that the low potencies of the broths were a crucial factor in Pfizer's failure to isolate or recover tetracycline (Dr. Stodola, Tr. 1942-45; Dr. Johnson, Tr. 2411; Dr. Grove, Tr. 2872-74; CX 37, pp. 77-81).

Patent Examiner Lidoff testified:

Q. Now, would you have considered Pfizer's test broth containing a potency of let us say 5.2 micrograms by biological assay as truly representative of Example 28 when the patent listed 274 micrograms per milliliter as the antibiotic potency obtained from that example?

A. No. To be a proper showing, it should have duplicated the conditions and normally the results of the patent example. (Tr. 11508-09.)

To be a proper duplication of Niedercorn Example 28, the Pfizer test broths should have at least approximated the potencies of the Duggar and Niedercorn patents. If this could not be accomplished, Pfizer should have reported to the patent examiner, should have disclosed its inability to achieve the results the patents should have obtained, and should have disclosed the earlier Niedercorn Example 1 information. These broths should not have been submitted to the patent examiner as truly representative of the patented broths. Patent Examiner Lidoff testified:

I would have been interested in any deviation from the disclosure of that example. (Lidoff, Tr. 11604.)

The affidavit of Dr. Tanner, prepared by Werner Hutz and Dr. Murphy, and signed by Dr. Tanner, misrepresented an important fact regarding the pH ("pH" is the measure of acidity or alkalinity of a broth or solution. When the pH of a solution is below 7, the neutral point, such solution is acidic; when above 7, it is alkaline. Tanner, Tr. 4209-10) of the Niedercorn fermentation that was material to the patent examiner's determination of whether Niedercorn Example 28 had in truth been duplicated. The Tanner affidavit, after describing the chemical content of the broth medium, stated (CX 4, p. 54):

* * * The fermentation medium was adjusted with sulfuric acid to a pH of approximately 6.7, since it was found to be higher than recommended by Niedercorn as optimum for fermentation. Twenty-five gallons of this medium was placed in a 50-gallon stainless steel fermentor (as above) and the medium was sterilized at 120 degrees C. for 20 minutes. It was then seeded with 5% by volume (5 liters) of the inoculum prepared as indicated directly above. The mixture was agitated and aerated under aseptic conditions * * * for a period of 40 hours.

The affidavit thus advised the Patent Office that the entire fermentation was conducted at a pH of 6.7. The actual fermentation commences after sterilization and after inoculation with the

microorganism (Murphy, Tr. 11685-6). This figure of 6.7 was the exact center of what the Niedercorn patent gives as the optimum or best range for pH for all fermentation examples described therein. The Niedercorn patent states:

*** for maximum growth, it is necessary that the pH of the fermentation medium be controlled within rather narrow limits. Highly effective growths may be obtained with the range of about 5.0 to 8.0. Best results are obtained within the range of approximately 6.4 to 7. (CX 2, col. 3, lines 16 *et seq.*)

In fact, Dr. Tanner's laboratory notes show that he began fermentation (at 1:30 a.m.) with the pH at 8.1 (CX 61, Tr. 4001-03). Six and one-half hours later, Dr. Tanner returned to the laboratory and found the pH still at 8.1 (Tanner, Tr. 4017, 4212-13; CX 61E). Dr. Tanner then adjusted the medium with sulphuric acid to bring the pH value down to 7.1 (Tanner, Tr. 4210-15). During this first six and one-half hours of fermentation, it was observed that no growth of the organism occurred (Tanner, Tr. 4218; CX 61E, 5th column from left headed "Myc.")

Pfizer's representatives failed to disclose this deficiency of the Niedercorn fermentation 1771B to Patent Examiner Lidoff (Tanner, Tr. 4220). Instead, Pfizer's representatives drafted the Tanner affidavit to show that the Niedercorn fermentation was conducted throughout at the best possible pH for antibiotic growth. In describing the other test broth—the Duggar fermentation where no pH problems were encountered—the Tanner affidavit correctly reported the pH readings both before and after sterilization of the medium (CX 4, p. 52, lines 5-6).

Patent Examiner Lidoff testified that if he had been told of the high pH, he would not have accepted that fermentation as a duplication of Niedercorn Example 28 (Lidoff, Tr. 11511-12, 11605-6, 11608). Mr. Lidoff stated:

And normally we would expect that the precise conditions of the example would be duplicated to present a proper comparison. Any deviation therefrom without being put on the record would not be a proper presentation of the case. (Tr. 11606.)

Dr. Tanner himself admitted that his affidavit indicated that the pH of the Niedercorn fermentation was kept within the optimum limits (6.4 to 7.0) of the Niedercorn patent (Tanner, Tr. 4220-21; Dr. Waksman, Tr. 7356). He also admitted that the pH of 8.1 was outside the range for optimum growth (CX 33, p. 38) and that the proper pH during fermentation was a critical factor (CX 33, pp. 20-22). Dr. Tanner's testimony in this respect was confirmed by Dr. Waksman, a Pfizer witness, who testified that the pH of a fermentation was "very critical"

(Dr. Waksman, a Pfizer witness, was a fermentation expert and a former Nobel Prize winner, Tr. 7352, 7305), that a high pH made "a tremendous difference," and that "the growth of the organism and the production of the antibiotic would be considerably delayed (Dr. Waksman, Tr. 7331).

Although the high pH may not have been Dr. Tanner's fault, the fact is that the Patent Office was not told about it. Mr. Lidoff testified that he would have expected to be informed of the high pH, as this meant that conditions stated in the Niedercorn Example 28 had not been duplicated (Lidoff, Tr. 11511-12, 11605-6, 11608). Patent Examiner Lidoff testified:

A. I am in no position to criticize experts. But, however, had it been called to my attention that there was a difference in pH, I would automatically have pointed out that that was not a proper comparison—that comparisons to be proper must be duplicates. (Tr. 11606.)

And further (Lidoff, Tr. 11608):

Q. My question to you, Mr. Lidoff—do you still say that a difference between 8.0 and 8.1 in pH is a significant difference in this field?

A. That is not what I said at all. What I said was that a test run at 8.1 would not in my opinion be properly representative of an example which in accordance with the specific disclosure of the Niedercorn patent obtained best results at a pH from 6.4 to 7.

Dr. Tanner himself, when questioned about the high pH, stated:

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.)

J. Pfizer's Misinformation to Lidoff Caused the Tetracycline Patent to Issue

The misrepresentations made to Patent Examiner Lidoff by the official representatives of Pfizer caused a patent on tetracycline to issue to Pfizer which, except for those misrepresentations, would not have issued.

The statements and affidavits submitted by Pfizer's representatives informed the patent examiner that no identifiable tetracycline was produced under the prior Duggar and Niedercorn patents (Lidoff, Tr. 11589, 11591), and the Pfizer Conover patent was, therefore, approved for issuance (Lidoff, Tr. 11593, 11595). Patent Examiner Lidoff testified.

A. In this case, the normal procedure was followed, and affidavits were produced which I understood to evidence the fact that no identifiable tetracycline was prepared in following the procedures of the patents that we had as references—namely, Niedercorn and Duggar. (Lidoff, Tr. 11503.)

A. * * * such evidence showed no tetracycline present in Duggar or Niedercorn, and hence my rejection, my speculative rejection, you might say, did

not have proper support, and based upon that, I dropped the rejection and allowed the application. (Tr. 11506.)

* * * * *

Q. Now, had Pfizer representatives informed you that identifiable tetracycline was in fact co-produced under the Duggar and Niedercorn patents, would you have taken the action you just described [allowed the Conover Patent]?

A. No. (Lidoff, Tr. 11507.)

An examination of the actual language used by Pfizer's representatives in their "Remarks" and affidavits verifies the understanding that the patent examiner derived from the Pfizer statements. Nowhere did Pfizer's representatives state or admit that tetracycline was actually present in Duggar and Niedercorn patent processes. All statements made by them indicated the contrary—that no tetracycline was coproduced under Duggar and Niedercorn because Pfizer's scientists had been unable to separate and identify any tetracycline in the broths or in the amorphous products.

In the "Remarks" filed in the Patent Office on November 29, 1954, Pfizer's representatives stated that the patent examiner was informed:

(1) " * * * that neither the Duggar or the Niedercorn patents contains any disclosure whatsoever of this important new antibiotic nor the slightest hint of the possible existence thereof." (CX 4, p. 34.)

(2) That there was "no reasonable basis" for the patent examiner's speculation. (CX 4, p. 34.)

(3) That the "available evidence is overwhelmingly contrary to the Examiner's assumption." (CX 4, p. 35.)

(4) That Cyanamid [Minieri] had stated that "there is no evidence of inherent production by the prior art processes." (CX 4, p. 35.)

(5) That Cyanamid who has manufactured tons of Aureomycin "failed to discover any tetracycline in such large-scale manufacture" although Cyanamid devoted extensive research to the properties of Aureomycin. (CX 4, pp. 35-36.)

(6) That the Bogert affidavit describes his "unsuccessful efforts to recover products clearly identifiable as tetracycline." (CX 4, p. 38.)

(7) That the Bogert affidavit shows that "it was not possible to recover any clearly identifiable tetracycline from the prior art broths." (CX 4, p. 39.)

(8) That "these results demonstrate that no appreciable amount of tetracycline is formed in the prior art fermentation processes,

thereby establishing that the Examiner's assumption is incorrect." (CX 4, p. 39.)

K. *Bristol's Taylor Affidavit Not Relevant to Pfizer's Application*

On January 3, 1955, about eight days before the Conover patent was publicly issued to Pfizer, Bristol filed the "Taylor" affidavit with the Patent Office in connection with the *ex parte* prosecution of its Heinemann application for a patent on tetracycline hydrochloride. In this affidavit Bristol stated that the numerous samples of commercial Aureomycin products tests contained from 2 to 4 percent tetracycline. The affidavit further stated that pure tetracycline had been separated from a sample of commercial Aureomycin (CX 9, pp. 171-72, 174-81; Dr. Taylor, Tr. 9269-70). (Dr. Taylor was a Bristol scientist who was employed in 1954 and 1955 as a patent agent for Bristol.) Based on this disclosure of the presence of 2 to 4 percent tetracycline in commercial Aureomycin, Bristol abandoned its claims to patent tetracycline as unpatentable (CX 9, p. 188).

The patent examiner did not recall whether or not he actually saw this Taylor affidavit before the Pfizer Conover patent was issued (Lidoff, Tr. 11513). In any event, the public issuance of the Pfizer Conover patent did not mean that the presence of 2 to 4 percent tetracycline was immaterial to the patentability of tetracycline. Patent Examiner Lidoff testified:

Q. Did you see this affidavit before the Conover Patent issued to Pfizer on January 11, 1955?

A. This I cannot remember, but the odds are very greatly against my having seen it.

Q. Did the public grant on January 11, 1955, of a patent to Pfizer on tetracycline mean that the presence of 2 to 4 percent tetracycline in commercial aureomycin was immaterial to the patentability of tetracycline?

A. No. And this I have answered before.

Q. Well, why was the Conover patent granting Pfizer a patent on tetracycline permitted to issue in view of this Bristol affidavit?

A. There are several answers to this, there are several facets to the answer.

First, and most important, information present or presented in applications of other parties cannot be used against a particular application. So that any information that might have been present in the Bristol application was not available. The Bristol application was in separate *ex parte* prosecution from this Conover application. They had been in interference. But after the interference was over, each case went its own way, and information present in one could not be used against the other. And, this, by the way, is true of all applications in the Patent Office. Information presented in other applications, whether known—even if known to me, could not have been applied against this particular application. Now, that is the overriding answer.

There are other answers too, in this particular case.

The information filed in the Bristol application would not normally have reached my desk within a short period of time. In addition to that, even if it had reached my desk, I would not have looked at it. The case would probably have been put in the files until it came up for action.

Additionally, the patent—the Conover application was out of my division, was in process of being printed, and would not have been removed from issuing as a patent except under very unusual circumstances. These circumstances were not present here. And lastly, as I have indicated before, this information was not published, and could not have been used for the rejection.

For the rejection I was then applying—that is then, prior to the issue of the patent—and would have caused a different rejection entirely based on a different section of the statute.

So there are multiple reasons, all of which, however, add up to the fact that the information was—could not be applied in the prosecution of this particular application. (Lidoff, Tr. 11513-15.)

L. Cyanamid's Misrepresentations

In November 1953, the patent examiner asked Cyanamid's patent attorney, Mr. 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 Cyanamid's Boothe-Morton patent application that 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 promotion 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 assignees 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. (CX 5, p. 47.)

Cyanamid's Boothe-Morton application contained claims to the product tetracycline (CX 5, p. 29). Patent Examiner Lidoff testified that the issue in which he was interested and about which he questioned Cyanamid's attorney was novelty. If tetracycline had been produced in a method making Aureomycin, either com-

mercial Aureomycin or in the fermentation processes of the Duggar and Niedercorn patents, the patent application would have been rejected (Lidoff, Tr. 11517-19, 11522-23).

The above-quoted remarks by Cyanamid's attorney advised the patent examiner that there was no tetracycline produced in Cyanamid's commercial operations and no tetracycline produced in any Aureomycin fermentations. 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. If Cyanamid's patent representative did not know the true facts, he was, nevertheless, under a duty to know them and under a duty to reveal the truth of the patent examiner.

During the second interference, Cyanamid's representative made additional statements to the Patent Office denying that tetracycline was inherently produced under Duggar and Niedercorn. On June 14, 1954, Cyanamid's representative stated in its Minieri application:

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. (CX 12, p. 36.)

On August 23, 1954, he further stated to the Patent Office:

Although Duggar, Niedercorn, and others have described fermentation processes employing strains of Aureofaciens, it does not appear that tetracycline was produced. (CX 12, p. 381.)

Speculation as to the probable inherent production of tetracycline in the Duggar and Niedercorn fermentations is not a proper basis for denying the present applicants patent protection in return for their contributions to the art. (CX 12, p. 382.)

The present situation differs from the one referred to above principally in that there is no evidence that tetracycline was inherently produced by the prior art processes of Duggar, Niedercorn, Sobin, or others. (CX 12, p. 383.)

And he categorically stated:

* * * Undoubtedly, a product claim will issue as a result of the present interference. (CX 12, p. 384.)

Cyanamid's representative thus informed the Patent Office that the inherent production of tetracycline did not take place under the Duggar and Niedercorn processes and that tetracycline was, therefore, novel and patentable.

M. Cyanamid's Knowledge Concerning Tetracycline

Cyanamid knew during 1954 that Aureomycin contained tetracycline. Analyses of Aureomycin "beers" (fermentation broths) by Cyanamid on January 20, 1954, showed "tetracycline in five (5) of the six (6) samples tested." (CX 111A.) Between January and March 1954, two different departments of Cyanamid worked on the "determination of tetracycline in chlortetracycline." About "three (3) percent tetracycline was found to be in Aureomycin." (CX 79A.)

Sometime in February 1954, Cyanamid determined that its analytical standard, by which the purity of Aureomycin was to be measured, contained tetracycline (CX 80).

In February 1954, Cyanamid's Director of Mycology Research, Dr. Bohonos, sent a memorandum to Dr. J. H. Williams, Cyanamid's Director of Chemical and Biological Research, that reported as much as 6 percent of tetracycline in some old Aureomycin prepared in 1948 (CX 111B). This document carried the notation "All copies ret'd and destroyed"; however, Dr. Williams kept his copy, since his initials appear on the document. This document shows that a copy was circulated to five other of Cyanamid's scientists, and to Mr. Edelblute, Cyanamid's house patent attorney who was representing Cyanamid at the Patent Office.

In March 1954, Cyanamid developed a method for determining the tetracycline content of Aureomycin and recommended that this method be used "by Dept. 519 as a routine assay." (CX 79B-D.) Two old samples of Aureomycin that were produced in the very beginning when Aureomycin was tentatively called "Duomycin" were found in February 1954 to contain tetracycline (CX 110B). Three samples of current Aureomycin tested in March 1954, were found to contain about 4 percent tetracycline (CX 114).

By the middle of 1954, the presence of tetracycline in Aureomycin was a well-known fact within Cyanamid (CX 79B, 80, 111A, 114). However, Cyanamid did not correct its earlier categorical statement made to the Patent Office in December 1953, that it had not made any tetracycline, inadvertently or otherwise, in its Aureomycin operations. In fact, during the summer of 1954, while the second interference was in progress, Cyanamid's representative, in papers filed with the Patent Office, continued to deny any inherent production. Cyanamid's knowledge was exactly contrary to its Patent Office statements.

N. *Cyanamid's Misrepresentations and the Withholding of Information Misled the Patent Examiner*

Patent Examiner Lidoff testified that if Cyanamid had informed him during the second interference, in a paper available to all the parties, that Aureomycin "contained two (2) to four (4) percent tetracycline," he "would have used that as a basis for rejecting all applications claiming the compound tetracycline." (Lidoff, Tr. 11519.) He further testified that his later handling of the Pfizer Conover application would have been different if Cyanamid had revealed this information to him—he would not have issued the patent (Lidoff, Tr. 11520).

Patent Examiner Lidoff's discussion with Mr. Edelblute was "not limited to commercial [A]ureomycin, but also involve[d] the fermentation processes of the type in Niedercorn and Duggar. . . ." (Lidoff, Tr. 11523.) Therefore, had Cyanamid advised the patent examiner during the second interference that the Duggar and Niedercorn fermentations contained tetracycline and that commercial Aureomycin contained tetracycline, the Pfizer Conover patent application would have been barred on two grounds: that is, tetracycline was not novel and was unpatentable because (1) it was produced under the processes of prior patents, and (2) it was available to the public prior to the filing of the Conover application (Lidoff, Tr. 11519–20, 11523).

O. *Questions Suggested by the Court and Answers by Lidoff*

The following questions were suggested by the Court (*American Cyanamid Co., supra*) as highly pertinent to the present inquiry:

To what extent was Examiner Lidoff aware of inherent coproduction of tetracycline in aureomycin broths and in the finished product?

Was he concerned only about coproduction in aureomycin as a finished product, or was his inquiry also directed to coproduction in aureomycin fermentation broths?

Was the hearing examiner correct or incorrect in his finding that if Lidoff had known that old aureomycin contained from two to five percent of tetracycline, he nevertheless would have granted the patent?

Did Lidoff consider any amount of coproduction under ten percent to be immaterial?

Why did Lidoff request tests by Pfizer of Niedercorn Example 28, rather than requesting tests of others of the forty-four Niedercorn examples, at least one of which (Example 1) the Commission found would have disclosed five percent coproduction?

Was Lidoff interested in establishing only that the prior art processes did or did not produce tetracycline in "appreciable" amounts, making possible its prior recovery as a therapeutic product? Was this his purpose in setting up the test of Example 28? If so, what did he consider to be an "appreciable amount" of tetracycline?

Was the hearing examiner correct in his conclusion that Lidoff knew "for more than a year prior to the decision on the second interference that fermentation broths produced under Dugger and Niedercorn usually contained tetracycline," or was the Commission correct in its conclusion to the contrary?

Did Lidoff draw a distinction as to the significance of coproduction as between product and process applications, as found by the hearing examiner, or was the Commission correct in reaching its contrary conclusion?

Did Lidoff see the "Taylor affidavit" filed by Bristol January 3, 1955, six days before the patent was issued? If so, what significance did he attach to its contents?

Would Lidoff's decision to grant the patent have been different if Cyanamid had revealed that it was in error in its prior assurances that there was no coproduction of tetracycline in aureomycin? Or was he already aware of the facts which the Commission found to have been withheld by Cyanamid?

Finally, the ultimate questions are: Did Lidoff receive all the information that he requested from Pfizer? And was Lidoff misled and deceived by Pfizer and Cyanamid and did he grant the tetracycline patent as the result of such deception?

It would seem that the answers by Examiner Lidoff to these questions might settle conclusively the issue as to whether Pfizer and Cyanamid made misrepresentations to the Patent Office and withheld essential information, thereby deceiving Lidoff into granting a patent which otherwise never would have been approved.

Although the answers to the above questions are somewhat repetitious of previous statements, they are deemed to be so relevant and important to the present inquiry as to merit this separate presentation. The exact questions as asked by complaint counsel and the answers as given by Mr. Lidoff are recorded on pages 11527 to 11535 of the transcript, as follows:

Q. Mr. Lidoff, I want to ask you if at the time the notice of allowance was issued in Pfizer's Conover application and prior thereto, to what extent were you aware of inherent coproduction of tetracycline in aureomycin broths and in the finished product?

A. I was not aware of such information, at least in any available form that could be applied in rejecting the application.

Q. The second question of the Court.

In handling applications, including Pfizer's Conover application, for a product patent on tetracycline, were you concerned only with co-production in aureomycin as a finished product, or was your inquiry also directed to co-production in aureomycin fermentation broths?

A. Overall I was interested in the prior production in any manner of tetracycline, specifically in this interest the production of tetracycline in conjunction with aureomycin, in view of the references which dealt with, at least ostensibly dealt with the production of aureomycin.

Q. Was the Federal Trade Commission Hearing Examiner that handled this case initially correct or incorrect in his finding that if you had known that old aureomycin contained from two to five percent tetracycline, you would nevertheless have granted the Pfizer tetracycline patent to Pfizer?

A. Well, as I pointed out before, while it would have been based on a different portion of the statute, I would not have allowed the Conover patent had I known that prior commercial aureomycin actually contained tetracycline, noting, of course, that this is a different rejection than the rejection that we have been discussing which I did make.

Q. Which you did what?

A. Which I did make. That the rejection in the file is a different rejection than that which would have been raised had this been known as a fact.

Q. Next question of the Sixth Circuit Court of Appeals.

Did you consider any amount of co-production of tetracycline in aureomycin under 10 percent to be immaterial in your handling of the Pfizer application for patent on tetracycline?

A. Well, that sentence is a little involved. No, I did not consider that production of any amount under 10 percent to be immaterial because—

Q. Is that immaterial?

A. Immaterial—because the production of any amount regardless of the numerical value would in my opinion have at that time properly supported the rejection. In other words, there is no numerical limitation to the amount of tetracycline produced. The important factor, in my mind, was any tetracycline produced.

Q. Why did you request tests by Pfizer of Niedercorn Example 28, if you did, rather than requesting tests of other examples among the 44 listed in the Niedercorn patent—and this is the Court's question—at least one of which, Example 1, the Commission found would have disclosed 5 percent co-production.

A. This requires some generalization here.

First of all, a patent examiner does not require tests. A patent examiner makes a rejection and in order to overcome this rejection, an applicant may, if he desires, present so-called tests or comparisons or any other data normally in affidavit form.

It is not the function of the patent examiner either to require tests or to point out specifically what tests should be made. Normally, however, a compromise has to be reached in view of the facilities available to the applicant for making the tests, and none are available to the patent examiner to check the tests. Normally a compromise is reached, and applicants present affidavits, present tests and comparisons, and based upon these an Examiner makes up

his mind, realizing that they are not necessarily the best or the ultimate in comparisons and in testing.

It is a question of working out the best possible compromise.

Now, I will say further that an Examiner will, in discussion, attempt to select from tests presented to him, or from data presented to him, if so asked—will attempt to point out the more convincing evidence. However, the selection of the test is normally in the province of the applicant.

Q. Well, did you limit Pfizer to Example 28?

A. Definitely no, I would not have. Now, remember, I don't recall precisely—I cannot. But I would not have limited testing to any example. I might have suggested that that looked the most promising, but I would not have limited the test to that example.

Q. Now, this is another question of the Sixth Circuit, and I will read it.

In your handling of the Pfizer Conover application for a patent on tetracycline, were you interested in establishing only that the prior art processes did or did not produce tetracycline in appreciable—and that is in quotes—amounts, making possible its prior recovery as a therapeutic product.

A. First of all, I was not—I would not have been interested in recovering a therapeutic product. The claim was directed to a compound per se, not to a therapeutic product. So that my interest would have been identification of the material tetracycline as present.

However, we run into some semantics here—and I know we will further on, as to recovery of appreciable amounts and so forth—and I might summarize that my interest was in determining whether or not the material tetracycline was present.

However, at that time, at least, most methods of identifying and determining the presence of this material would have in the broadest sense been encompassed by the word "recovery". You normally in order to identify something recover it to the extent of at least separating it from some of its impurities. So that while we are bandying words back and forth, the important factor in my view of patentability was that if any identifiable amount of the material were present, a valid patent could not issue, and regardless of what language we end up using, this is what I was after.

Q. I see.

Was the Federal Trade Commission Hearing Examiner correct in his conclusion that you knew "for more than a year prior to the decision on the second interference" that fermentation broths produced under Duggar and Niedercorn usually contain tetracycline, or was the Federal Trade Commission correct in its conclusion to the contrary?

A. The answer is I did not know.

Q. Did you draw a distinction as to the significance of co- [sic] as between product and process applications as found by the FTC Hearing Examiner, or was the Federal Trade Commission correct in reaching its contrary conclusion?

A. Simply speaking, I did not make a distinction in my mind between the two. This will probably later demand some explanation as to these office actions dealing with fermentation processes and products. If you wish the explanation now, I can put it into the record.

Q. Well, when you say you did not draw a distinction between the two, you mean between the product application and the fermentation process application.

A. Correct.

Q. Was the amount—rather, was the co-production of any tetracycline equally a factor in both these types of applications?

A. No, not equally. In a product claim, the presence of the tetracycline was a determining issue. In a process claim, the process parameters were the important thing, and the product so produced of less significance. So there is a great distinction as to the weight to be given to this co-production.

Q. Is any—is the co-production of any tetracycline relevant to a product application?

A. In my opinion, the production of any tetracycline is the most important factor in an application containing claims to the product tetracycline.

Q. The next question I have concerns the Taylor affidavit which you have earlier answered. [See Section K of this Initial Decision On Remand, p. 646.]

The next question I will ask you is a question posed by the Sixth Circuit Court of Appeals as follows:

Would your decision to grant the Pfizer Conover patent have been different if Cyanamid had revealed that it was in error in its prior assurances that there was no co-production of tetracycline in aureomycin, or were you already aware of the fact that aureomycin contained tetracycline?

A. A, I was not aware of the fact.

Q. I didn't get that answer.

A. A—I was not aware of the fact that aureomycin actually contained tetracycline. And B, as I pointed out before, the availability of this knowledge, the form in which the knowledge was available, would have been the most important thing. That is to say, it has to be in a publication that could be used. The fact that Cyanamid may have admitted it in a record, in a Cyanamid application, would not have been of significance in the prosecution of the Conover application once it was separated from the interference.

Q. Why?

A. Because as I pointed out in the Patent Office information in one application, an application assigned to an assignee, cannot be employed to reject another application—an application of a different assignee. The basis for such rejections are [sic] normally publication.

Now, that would have to do with published matter.

Now, in addition to that, we have not separated from that particular question whether this information had to do with aureomycin produced in accordance with Duggar and Niedercorn, and that commercially available. That is, we had to split that also.

Q. Well, now, if Cyanamid had revealed during the second interference proceeding between Cyanamid, Pfizer, and Bristol, that it was in error in its prior assurances, that there was no co-production in aureomycin, would your decision to grant the Pfizer Conover patent have been different?

A. The answer is yes, and let's break it down into two parts.

If they had admitted during the interference that following Duggar or Niedercorn a broth would be produced which contain [sic] tetracycline, then I would have maintained the rejection which we did present based upon the Duggar and Niedercorn application.

If, on the other hand, the admission was that commercial aureomycin previously sold to the public had contained tetracycline, then the rejection would have been a different rejection based on a different section of the statute, but nevertheless would have prevented issuance of the patent.

Q. Does that include the Conover patent?

A. Yes—it includes all of them. As long as they were in interference, it would include any application then in that interference—because the information would then have been available to all parties, and they could have had a chance to rebut it ex parte.

The cross-examination of Mr. Lidoff, which is recorded on pages 11535 to 11614 and from 11725 to 11727 of the transcript, resulted in no substantial change in Mr. Lidoff's testimony from that given on direct examination.

VIII. CONCLUSIONS

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

2. This proceeding is in the public interest.

3. Representative officials of Pfizer made false and misleading statements to officials of the United States Patent Office and suppressed and withheld information from them, all of which was relevant and material to the consideration of the application by the officials of the Patent Office for a patent on tetracycline, thereby causing those officials of the United States Patent Office to issue a patent on tetracycline that otherwise never would have been issued.

4. Official representatives of Cyanamid made false and misleading statements to officials of the United States Patent Office and suppressed and withheld information from them, all of which was relevant and material to the consideration by the officials of the application for a patent on tetracycline, thereby aiding Pfizer in securing a patent on tetracycline that otherwise never would have been issued. Cyanamid engaged in this conduct with the knowledge that it would receive a license from Pfizer if a patent on tetracycline was issued to Pfizer.

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

IX. ORDER ON REMAND

It is ordered, That respondents Chas. Pfizer & Co., Inc., and American Cyanamid Company, and their officers, agents, repre-

sentatives, and employees, in connection with the offering for sale, sale, or distribution, in commerce, between and among the several States of the United States and in the District of Columbia, of tetracycline, be, and the same hereby are, legally bound by the prohibitions and requirements of paragraphs three (3) through eight (8) of the Commission's Order herein of December 17, 1963 [63 F.T.C. 1747, 1910-1911].

OPINION OF THE COMMISSION

SEPTEMBER 29, 1967

BY REILLY, *Commissioner*:

An order to cease and desist was issued by the Commission in this matter on December 17, 1963, [63 F.T.C. 1747]. Thereafter the order was reviewed by the United States Court of Appeals for the Sixth Circuit, and in an opinion issued June 16, 1966 [8 S.&D. 248], the court vacated and set aside the Commission's decision and remanded the entire proceeding to the Commission for a *de novo* hearing on all issues without the participation of Chairman Dixon.

The complaint herein, filed July 28, 1958, charged respondent Pfizer with making false, misleading, and incorrect statements to, and withholding material information from, the United States Patent Office for the purpose and with the effect of inducing the issuance of a patent on tetracycline, a broad-spectrum antibiotic. The complaint also alleged that Bristol and Cyanamid withheld from the Patent Office material information in the course of the prosecution of patent applications, as a result of which Pfizer was aided in obtaining its tetracycline patent, and that Cyanamid, Bristol, Squibb and Upjohn solicited and accepted licenses from Pfizer under the tetracycline patent, knowing that material information had been withheld from the Patent Office by one or more of the respondents. The complaint further alleged that all five respondents fixed and maintained prices of broad-spectrum antibiotics, including tetracycline, through conspiracy and combination.

On October 31, 1961, Hearing Examiner Robert L. Piper filed an initial decision holding that the evidence failed to establish that respondents had engaged in any of the unlawful practices alleged in the complaint. On appeal, this initial decision was vacated and set aside and on August 8, 1963, the Commission entered its own findings of fact, conclusions of law and opinion. It found that Pfizer, in securing its tetracycline patent, had deliberately

made false and misleading representations to, and withheld information from, the Patent Office and it concluded that this conduct amounted to "unclean hands," "inequity," and "bad faith" vis-a-vis the Patent Office.¹ The Commission further found that Pfizer asserted monopoly rights under its patent in order to prevent competition in the tetracycline market and that the effects of those acts have been to restrain competition, to foreclose a substantial market, and to create a monopoly in the manufacture and sale of tetracycline in violation of Section 5 of the Federal Trade Commission Act.

The Commission also found that Cyanamid made erroneous representations to the Patent Office concerning matters bearing on the patentability of tetracycline, and that although Cyanamid soon discovered that these representations were inaccurate, it did not disclose this fact to the Patent Office until after the tetracycline patent had been granted to Pfizer, thereby aiding the latter in its efforts to obtain a patent. The Commission ruled that Cyanamid's acceptance of a license from Pfizer to make and sell tetracycline with knowledge that it had made false statements of fact to the Patent Office which bore directly on the question of patentability of tetracycline, constituted an illegal attempt on its part to share in a monopoly on tetracycline and amounted to a combination in restraint of trade. Similar charges against Bristol, Squibb and Upjohn were dismissed.

On the issue of price fixing, the Commission held that the record as a whole sustained the charge that all five respondents fixed and maintained the price of tetracycline in substantial markets through conspiracy and combination.

In its final order, entered December 17, 1963, the Commission directed Pfizer to license its tetracycline patent to any domestic applicant on a 2½ percent royalty basis and to provide the licensees with certain technical know-how. Under identical terms, Cyanamid was directed to grant licenses for tetracycline production under two Aureomycin patents. All five respondents were prohibited (by order issued in August 1963) from entering into price-fixing agreements and each respondent was directed to redetermine its tetracycline prices.

All respondents appealed from this decision to the United States Court of Appeals for the Sixth Circuit, challenging the Commission's findings, conclusions and order on both the patent and pricing phases of the case. They also claimed that they had been

¹ The Commission was also of the opinion that Pfizer was guilty of common-law fraud but found that such a holding was unnecessary to its disposition of the case.

deprived of a fair hearing by reason of Chairman Dixon's participation in the decision. In an opinion filed June 16, 1966, the court held that Chairman Dixon was disqualified to sit in the case and, on the basis of that holding, remanded the case for a *de novo* consideration of the record without the Chairman's participation. Because of the remand, the court expressed no opinion as to whether the Commission's findings and decision with respect to the price-fixing issue were supported by substantial evidence. It did, however, pass upon two other issues for the assistance of the Commission on remand. It held first of all that "assuming the facts as found by the Commission to be supported by substantial evidence, the Commission has jurisdiction to require as a remedy the compulsory licensing of the tetracycline and Aureomycin patents on a reasonable royalty basis." And secondly, it held that the Commission's decision to the effect that the tetracycline patent was issued as a result of improper conduct on the part of Pfizer and Cyanamid, as well as the corresponding portion of the order to cease and desist, was not supported by substantial evidence on the record considered as a whole.

Certain background information is necessary to an understanding of the patent phase of this matter and to the court's ruling with respect thereto. The following facts which are not in dispute are taken in substantial part from the findings as to the facts made by the Commission in its original decision.

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 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. The antibiotics with which this case is concerned are known, beginning with the discovery of Aureomycin, as broad-spectrum antibiotics because they are allegedly effective against a wider range of bacteria, including both gram-positive and gram-negative bacteria.

At the time the complaint issued, there were four broad-spectrum antibiotics on the market: chlortetracycline, oxytetracycline, tetracycline and chloramphenicol.² Each of these is patented. Cyanamid, which is the owner of the patent on chlortetracycline and the sole manufacturer and seller of this product,

² Parke-Davis & Company (not a party to this proceeding) is the patentee of chloramphenicol, which has been sold and manufactured by this concern since 1949 under the trade name "Chloromycetin."

introduced it on the market in 1948 under the trade name "Aureomycin." Pfizer holds the patent on oxytetracycline and is its sole manufacturer and seller. This antibiotic reached the market in 1950 under the trade name "Terramycin." Tetracycline is the only one of the four antibiotics sold by more than one firm. As a result of the settlement of a patent interference proceeding, Pfizer, the owner of the tetracycline patent, licensed Cyanamid to manufacture and sell tetracycline. Later on, Bristol, Squibb, and Upjohn were licensed by Pfizer upon settlement of infringement suits brought by the latter.

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. Other factors which determine the type and amount of antibiotic substance to be produced are the chemical ingredients of the broth and the conditions under which the fermentation takes place.

The yield of antibiotic content per milliliter of a fermentation broth is commonly called "potency." Potency is usually measured in terms of micrograms (mcg.) per milliliter (ml.). The term "potency" is also used to describe the antibiotic content of solid products that are recovered from a broth. Potency is then stated in terms of micrograms (mcg.) per milligram (mg.).

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

Tetracycline can be made either by fermentation or 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.

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 patent 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.

Prior to 1952, the chemical structures of Aureomycin and Terramycin were unknown. Aureomycin, for instance, was described in the Duggar Patent as an "antibiotic substance" and was identified in terms of secondary chemical properties. 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 October 23, 1952, Pfizer filed on behalf of Conover an application with the Patent Office for a patent on the deschlorination process and the compound tetracycline *per se*. Thus the product claims were not limited to the tetracycline as produced by Conover's process but were broad enough to read on tetracycline and its salts produced by any process and in any amount.³

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 September 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. As

³ The product claims as they were carried over into a continuation-in-part application read as follows (CX 4, p. 8):

"1. A compound chosen from the group consisting of tetracycline, the mineral acid salts of tetracycline, the alkali metal salts of tetracycline and the alkaline earth metal salts of tetracycline.

2. Tetracycline.

3. Mineral acid salts of tetracycline.

4. Alkali metal salts of tetracycline.

5. Alkaline earth metal salts of tetracycline.

6. Tetracycline hydrochloride."

stated above, the patent applications filed by Pfizer and Cyanamid disclosed a process for manufacturing tetracycline by hydrogenating Aureomycin. The Minieri application, however, was apparently the first discovery that tetracycline could be made by direct fermentation. This application 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. It was on the basis of this information that the patent examiner handling the various tetracycline applications speculated that tetracycline was coproduced with Aureomycin in the processes disclosed in the Duggar and Niedercorn patents.⁴

An application for a patent on tetracycline and a process for 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 it appeared that tetracycline had been coproduced with Aureomycin in the Duggar and Niedercorn fermentations.

On November 16, 1953, Harvey Edelblute, Cyanamid's house counsel who was then prosecuting the Boothe-Morton application, had an interview with H. J. Lidoff, the patent examiner who was also handling the Cyanamid and Pfizer tetracycline patent applications. Lidoff inquired about the possibility that tetracycline may have always been concomitantly produced by Cyanamid in its production of Aureomycin, and in response to this inquiry, Edelblute filed a statement in December 1953 assuring the examiner that Cyanamid had investigated the matter and had determined that coproduction did not occur.

On December 28, 1953, Lidoff declared an interference between Pfizer's Conover application and Cyanamid's Boothe-Morton application. 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. This interference was terminated on February 9, 1954, following the execution of an agreement between Pfizer and Cyanamid providing 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 as to priority of invention of tetracycline, Cyanamid conceded that the Pfizer (Conover)

⁴ On November 4, 1953, Cyanamid purchased Heyden's antibiotic division thereby acquiring the rights to the Minieri tetracycline patent application.

application had priority in time and withdrew its Boothe-Morton application.

A second interference was declared by Lidoff on March 2, 1954. 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 this second interference was to determine who had priority on the discovery of tetracycline hydrochloride and the parties to it were Pfizer (Conover application), Bristol (Heinemann application) and Cyanamid (Minieri application).

On October 14, 1954, Examiner Lidoff granted motions by Pfizer and Cyanamid to dissolve the second interference and, on his own motion, ruled that tetracycline hydrochloride was not patentable to any of the parties because it appeared that tetracycline and its hydrochloride were inherently coproduced in the fermentation processes described in the Duggar and Niedercorn patents. The patent examiner stated in this connection:

* * * The interference count is unpatentable over the disclosures of Duggar US 2,482,055, Sept. 13, 1949 and Niedercorn US 2,609,329, Sept. 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 (see page 1, lines 5 to 20 and lines 24 to 28 and pages 12, 16, 17, 18 and 19 of Minieri et al S.N. 382,637). Minieri et al clearly and specifically disclose that the microorganism used to prepare tetracycline belongs to the Duggar et al US 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 USPQ 411). (Emphasis in original.)

On October 15, 1954, one day after the dissolution 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, 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" (CX 55). 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,⁵ 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 (CX 57).

Pursuant to instructions Tanner conducted fermentations of all the process examples in Duggar and Niedercorn and found that only two broths possessed significant antibiotic potency. Both of these broths were prepared in accordance with the specifications set forth in Niedercorn Example 1. One of these broths possessed an antibiotic potency of 75 micrograms per milliliter and the other, 30 micrograms per milliliter. Taking the higher potency broth, Bogert applied a modified Pidacks procedure and obtained a number of fractions which were found by paper chromatography⁶ to contain tetracycline (CX 58). Bogert testified that these

⁵ 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 a 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.

⁶ 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 the standards. Paper chromatography can also be used to determine the percentage of tetracycline present in a mixture by measuring the zone of inhibition of the bacteria test organism.

tests showed tetracycline to be present and to be present in quantities "of approximately five percent" (Tr. 4412).

The record also shows that in September of 1954, 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 Example 28 medium and had found the resulting broths to be less than 10 micrograms per milliliter (RPX 12B). These broths were so poor in antibiotic potency that they were classified as containing no Aureomycin or tetracycline (Tr. 4129-4130). On the other hand, as in the aforementioned October work, Tanner obtained potencies from Niedercorn Example 1 that exceeded 70 mcg./ml.

On November 24, 1954, Examiner Lidoff officially rejected the product claims in the Conover application (then in an *ex parte* status) by carrying over *verbatim* his ruling in the second interference that the claims were unpatentable because tetracycline was apparently coproduced in the Duggar and Niedercorn processes. He did allow the process claims, however, recognizing that Conover's method of converting chlortetracycline (Aureomycin) into tetracycline merited patent protection. The misrepresentations and withholdings that are involved in this case concerned only the product claims, which as previously noted, were broad enough to cover the compound "tetracycline" produced by any process and in any amount.

On November 29, 1954, Werner H. Hutz, Pfizer's outside patent counsel handling the Conover application, and Dr. 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 coproduction were correct. There are numerous court decisions establishing the rule that "novelty is not negated 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.

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 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.

After the oral interview of November 29, 1954, Murphy 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 three recovery procedures described in the Bogert-Walsh, Minieri, and Heinemann applications. After these tests had been completed, Pfizer submitted affidavits to the patent examiner, executed by Bogert and Tanner, informing him that they had not been able to recover products clearly identifiable as tetracycline from the Example 28 fermentation broths. After examining the affidavits, the patent 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 tests 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 amount 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.

Bogert's supplemental affidavit recited that he had applied an acid color test which should show whether an amorphous product recovered from one of the broths 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.

On the basis of 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.

In holding that neither Pfizer nor Cyanamid was guilty of any impropriety in dealing with the Patent Office, Hearing Examiner Piper (in the first initial decision in this matter) was of the opinion that Lidoff's rejection of the tetracycline product claims was based on the speculation that tetracycline had imparted utility to commercial Aureomycin and therefore had been in prior public use or on sale, grounds for rejection under Section 102(b) of the Patent Code, 35 U.S.C. 102(b). He found that Lidoff was aware that tetracycline was inherently produced in Aureomycin fermentation broths and that he was interested only in whether tetracycline was present in commercial Aureomycin products. He reasoned 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. He further reasoned that since Lidoff had referred to those portions of Minieri which demonstrated the presence of tetracycline in quantities of 50 percent or more of the antibiotic present the patent examiner "must have assumed logically that this might have occurred under Duggar and Niedercorn and therefore was speculating that it might have been present in such substantial quantities" (Initial Decision, p. 57). He concluded that "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 percent tetracycline, the amount Pfizer requested the patent examiner to assume. Pfizer did not withhold or misrepresent any information concerning inherent production" (Initial Decision, p. 66).

The Commission, on the other hand, held that there was no basis in the record for the hearing examiner's finding that Lidoff had rejected the Conover application on the ground that tetracycline may have imparted utility to the commercial product

Aureomycin. It held instead that Lidoff had speculated that Conover had discovered a product which had already existed in prior art fermentation processes that were described in prior patents (Duggar and Niedercorn) as producing an "antibiotic substance" and for this reason lacked novelty and could not be patented under 35 U.S.C. 102(e) and (f). It specifically held in this connection that "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." According to the Commission, therefore, the purpose of the affidavit tests was to ascertain 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. It further found that Pfizer's representatives had argued to Lidoff that there was no reasonable basis for his assumption of coproduction and that, in response to this argument, the patent examiner stated 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. The Commission also found that although Lidoff may have believed that Niedercorn Example 28, because of its low chloride ion content, was the most favorable of the media for the production of tetracycline he was interested in the possible production of tetracycline in any of the Niedercorn examples.

The Commission's conclusion that Pfizer had violated Section 5 was based on the finding that Pfizer's representatives failed to disclose to Lidoff, although under a duty to do so, that Pfizer had discovered from previous tests that NRRL-2209 fermented in a Niedercorn Example 28 medium produced broths which were so poor in antibiotic potency that they were classified by Pfizer as containing no Aureomycin or tetracycline, whereas fermentation of NRRL-2209 in a Niedercorn Example 1 medium produced a broth of much higher potency which was found to contain tetracycline; that Pfizer's representatives withheld the fact that the broths used in the affidavit tests were unusually low in potency and that the pH of one of the broths exceeded the optimum limits prescribed in the patent during the first part of the fermentation; that Pfizer's representatives had falsely represented that "the

available evidence is overwhelmingly contrary" to the examiner's assumption of coproduction; that they falsely stated that the two broths described in Tanner's affidavit were "representative" of the Duggar and Niedercorn broths; and that they falsely stated that the recovery procedures used by Bogert were the best designed for recovering any tetracycline present in the test broths.

With respect to Cyanamid, the Commission held that this respondent had made false statements of fact to the Patent Office concerning the coproduction of tetracycline in commercial Aureomycin. It held that 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 fermentations, the denial by Cyanamid of such coproduction aided Pfizer in its endeavor to convince the patent examiner that tetracycline was a new product that did not exist in the prior art. Under these circumstances, the Commission found Cyanamid's acceptance of a license under the Conover patent constituted an illegal attempt on its part to share in a monopoly on tetracycline.

In its review of the Commission's decision the court expressed the opinion that only Lidoff could conclusively settle the issue as to whether Pfizer and Cyanamid had made misrepresentations and withheld essential information bearing on the question of the patentability of tetracycline. It pointed out that "with no testimony available from Mr. Lidoff, the hearing examiner and Commission drew opposite inferences and reached opposite conclusions as to what the patent examiner knew, intended, and required in the processing of the patent applications." The court therefore held that the decision of the Commission on the patent issue was based upon "inferences and speculations which are insufficient to constitute substantial evidence." It suggested that Lidoff be called "as a witness to testify as to facts known only to him with respect to material issues of great public interest in this proceeding."

After remand from the court, the Commission, by order of August 1, 1966 [70 F.T.C. 1763], reopened the proceeding and remanded it to the Chief Hearing Examiner for assignment to an examiner⁷ to begin hearings for the "sole and limited purpose of receiving the testimony of Patent Examiner H. J. Lidoff, and of any other witnesses who have heretofore testified, with respect to 'the issue as to whether Pfizer and Cyanamid made misrepresentations to the Patent Office and withheld essential information, thereby deceiving Lidoff into granting a patent which otherwise

⁷ Hearing Examiner Piper was no longer in the employ of the Commission at this time.

never would have been approved.' " Pursuant to these instructions, a hearing was held before Hearing Examiner Abner Lipscomb at which Mr. Lidoff was presented as a witness by counsel supporting the complaint, and Werner H. Hutz and Dr. Francis X. Murphy were presented as witnesses by Pfizer.

In an initial decision filed November 9, 1966 [p. 624 herein], the hearing examiner, relying principally on the testimony of Mr. Lidoff, made findings of fact which are in complete accord with the earlier findings of the Commission with respect to the state of Lidoff's knowledge concerning coproduction of tetracycline in prior art processes and with respect to the basis for Lidoff's rejection of the tetracycline product claims in the Conover application. Lidoff testified in this connection that as of December 9, 1954, and prior thereto he did not know as a fact that any tetracycline was inherently produced in the Duggar and Niedercorn patent fermentations; that he had speculated on the basis of information contained in the Minieri application that some tetracycline was present in the fermentation broths made pursuant to the teachings of Duggar and Niedercorn; that if tetracycline was inherently produced by these prior art processes and could be identified in the broths he was of the opinion that it lacked novelty and could not be patented; that Hutz and Murphy had vigorously denied at the time that such coproduction occurred; and that the factual question that he was attempting to get answered was whether identifiable tetracycline was or was not present in the broths of the Duggar and Niedercorn patents. Above all, he testified that had he been told by Pfizer that 5% of the antibiotic content of a Niedercorn Example 1 broth was tetracycline he would never have allowed the patent. He further testified that if he had known that commercial Aureomycin contained tetracycline he would have also rejected the Conover application on a different and additional statutory ground.

In his initial decision the hearing examiner, relying primarily on Lidoff's testimony, concluded that representatives of Pfizer and Cyanamid had made false and misleading statements to Patent Examiner Lidoff and had suppressed and withheld information from him all of which was relevant and material to his consideration of Pfizer's application for a patent on tetracycline. He further concluded that Pfizer's misrepresentations and withholding of essential information caused the Patent Office to issue a patent on tetracycline that otherwise never would have been issued and that similar conduct on the part of Cyanamid aided Pfizer in securing this patent.

Pfizer's Appeal

The first contention made by Pfizer on its appeal from Hearing Examiner Lipscomb's initial decision is that Lidoff's testimony was not based on his recollection of what occurred during his interviews with Hutz and Murphy and therefore should not have been admitted into evidence. In making this argument Pfizer relies on certain statements made by Lidoff on cross-examination which, according to Pfizer, establish that he was totally unable to refresh his memory. We find this argument to be wholly without merit. While Lidoff frankly conceded that after 11 years he could not recall the details of one interview out of several hundred, an examination of his testimony reveals that his recollection of the substance of what occurred in connection with the tetracycline application was quite clear. There is no basis for Pfizer's claim that his mind was a "complete blank" and that he "remembered absolutely nothing." Mr. Lidoff testified not only from a reconstruction of events based on the official Patent Office file, but also as he put it, "on what I know, my feelings and views of what patent practices were at the time" (Tr. 11,541). As the court observed, the answer to the question of whether disclosure of the 5 percent coproduction would have been material to Lidoff was something "known only to him." His testimony is unequivocal that he was interested in the coproduction of any amount of identifiable tetracycline and had he been informed by Pfizer that coproduction in fact occurred he would never have allowed the patent to issue. His testimony on this point is supported by his own written office action of November 24, 1954, *supra* p. 662, the language of which embraces any identifiable amount of coproduction of tetracycline. The hearing examiner found that Mr. Lidoff was entirely credible and that his testimony "which was presented clearly and unequivocally, explains the numerous factual problems that confronted both the Commission and the Court in their evaluations of the original record; and it supplements and explains clearly proven facts in the record." We agree with the examiner.

Pfizer next contends that Lidoff's testimony is entitled to little weight because it is inconsistent with the testimony of Hutz and Murphy and with the contemporaneous Patent Office record, *i.e.*, the Remarks drafted by Hutz which set forth the substance of the conference with Lidoff on November 29, 1954. This is a rather surprising argument since Lidoff's testimony corroborates in every significant detail the earlier findings of the Commission which were based on the Remarks. But Pfizer nevertheless con-

tends that Lidoff's testimony to the effect that he was interested in the coproduction of any identifiable tetracycline is in conflict with the Remarks (which he had reviewed and apparently approved) which, according to Pfizer, stated that he was interested only in the coproduction of larger quantities of tetracycline which could be recovered by procedures "then recommended for the recovery of useful amounts of tetracycline from fermentation broths." We do not agree. There would be an inconsistency between Lidoff's testimony and the Remarks only if words and phrases in the Remarks are taken out of context and given the meaning which Pfizer wants them to have.

Pfizer states in its brief that the Remarks describe Lidoff "as having no interest in 'useless trace amounts' of tetracycline * * * but his recent testimony is directly to the contrary. He now insists that, 'the proportion or amount was not significant. The presence was the important thing' * * * the 'percentage is insignificant' * * * ." When read in context, however, the memorandum of the conference between Lidoff and the Pfizer officials reveals, as Lidoff had testified, that the information which he had requested was whether tetracycline was present in broths produced pursuant to Duggar and Niedercorn. According to the Remarks, Pfizer's representatives had argued to Lidoff that the legal basis for his rejection was wrong and that the Conover claims could not be anticipated by a "wholly unrecognized occurrence of some ineffective amount of tetracycline." This certainly does not indicate that Lidoff had based his rejection on the assumption that large quantities or useful, effective amounts of tetracycline were coproduced by the prior art processes as Pfizer now contends. To the contrary, it is obvious that Lidoff's rejection had been based on the belief that the occurrence of even some "ineffective" amount of tetracycline (an amount which "would display none of the distinctive properties" of tetracycline in therapeutic form) would be sufficient to anticipate Conover's claim. Consequently, he would not have required proof that large quantities or therapeutically useful amounts of tetracycline could not be recovered unless he had been persuaded by Hutz's arguments that he was wrong as a matter of law.⁸ But the Remarks show that Lidoff did not change

⁸ When asked at the remand hearing what was meant by "ineffective amounts" Hutz testified that this "could be something more than appreciable but less than effective," an amount which would be insufficient to "display the distinctive properties that make tetracycline such an important advance in the art" (Tr. 11669), thereby contradicting Pfizer's definition of "appreciable" amounts as "amounts which have some usefulness, amounts which impart to the product in which they are contained the antibiotic effect of tetracycline" (Tr. 11589).

Dr. Murphy's testimony on this point is most revealing: "Q. Why were you talking with Mr. Lidoff about ineffective amounts if he was not interested in ineffective amounts? A. Well, he

his mind. They state that despite Hutz's 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."

Lidoff then explained, according to the Remarks, 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" and 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." It becomes quite clear at this point in the Remarks that the recovery or separation of tetracycline from the broths was to be made solely for the purpose of identification.

It is obvious from Lidoff's testimony that he believed that a separation of the substance was necessary for its positive identification:

Q. You stated that you considered these analytical techniques to be recovery procedures, is that so?

A. I said that in my view, the language "recovery" would also encompass procedures of this nature which separate the material from other materials in order to determine whether or not it is there.

* * * * *

Q. Now, isn't it a fact that many of these analytical techniques do not recover any product whatever, but actually destroy the product that they are looking for?

A. Completely analysis would obviously do that. Infra red would probably not recover. Yes, there are methods of identification that would not involve recovery. But as I said earlier, recovery is the preponderant method of identifying a material. That is when you identify materials, the normal procedure would be a form of recovery. The largest number of methods employed at that time would have been a form of recovery broadly (Tr. 11558-11559).⁹

The Remarks then state that "The Examiner made it clear that he would not insist on a categorical averment that the fermentation broths prepared according to the cited patents contained no tetracycline whatsoever." And the reason that Lidoff did not so insist was not because he was uninterested in even the most minute amount of tetracycline but because he appreciated "the

indicated that he was not interested in trace amounts, useless material—Q. Useless material. Ineffective amounts? A. Ineffective material * * * Q. You testified that he was interested in recoverable amounts. You testified that ineffective amounts were not recoverable. And yet you were arguing with him about amounts that were not recoverable. Why were you doing this? A. I don't recall" (Tr. 11709-10).

⁹ Lidoff also testified that he regarded paper chromatography as an identification procedure which involved the separation of a product from other materials in a mixture. (See Tr. 11560.)

impossibility of proving its non-existence." Here again the Remarks make it clear that Lidoff was interested solely in knowing whether tetracycline existed in the prior art fermentations.

The statement is then made in the Remarks that Lidoff was not "concerned about useless trace amounts which cannot be separated from the broths by methods now recommended for recovery of the new antibiotic." The key words in this clause are not "useless trace" amounts as Pfizer would have us believe. When read in context these words are meaningless. Lidoff was concerned with *identifiable* tetracycline and since he equated separation of tetracycline with positive identification of that substance the significant words in the sentence are "amounts which cannot be separated from the broths" by known tetracycline recovery procedures.¹⁰

We also find there is no substance to Pfizer's claim that there is evidence that Lidoff wanted Pfizer to use commercial or industrial type recovery procedures. The record conclusively establishes that Lidoff was interested in the separation and recovery of tetracycline in clearly identifiable form by whatever method it could be achieved.

We note first of all, despite Pfizer's argument to the contrary, that Lidoff is correct in his view that Craig countercurrent¹¹ is a recovery procedure as well as an analytical technique. Dr. Woodward, one of the scientists called by Pfizer, testified as follows with respect to Craig countercurrent:

Q. Is Craig Counter-current Distribution an analytical technique or a recovery procedure?

A. That is also an exceedingly valuable analytical technique, occasionally used for the recovery of materials in very small amounts (Tr. 4586).

The record also shows that after Lidoff had examined Bogert's first affidavit he required an explanation why further attempts were not made to separate and recover tetracycline from an amorphous product which had been separated from one of the test broths. This amorphous product which was extremely small and weak in potency was described as follows in Bogert's affidavit: "A total of 0.36 grams of material having a potency of about 260

¹⁰ As Lidoff pointed out in his testimony, the words in the Remarks are not his words but are the words of Pfizer's officials. It is clear, however, that the summary of what transpired at the conference is sufficiently accurate that Lidoff, having no reason to suspect that Pfizer might later place a different interpretation on them, could accept the Remarks without question.

¹¹ 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.

micrograms per milligram as chlortetracycline [Aureomycin] was obtained. 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." According to the Remarks, it was pointed out to Lidoff that the amount of material was so small and the potency so low "that it would be futile to attempt to recover identifiable tetracycline therefrom by *known procedures*" (emphasis added). And in a second affidavit Bogert stated that even if "the maximum possible proportion of the total potency due to tetracycline is 10 percent, 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" (emphasis added). It is quite obvious from the reference to "known procedures" and "any method" that Lidoff was interested in the separation or isolation of tetracycline by any procedure and that Pfizer's officials were well aware of that fact.

In light of this evidence we are not persuaded by the testimony of Hutz and Murphy and by Pfizer's contention based thereon that Lidoff was not interested in the recovery or separation of tetracycline by methods other than those which would be feasible for large scale use or which would permit direct recovery of tetracycline from fermentation broths. Also Pfizer's contention that Lidoff was not interested in certain isolation procedures which it has characterized as sensitive analytical techniques must fall in the face of this evidence and the testimony of Dr. Murphy. It is noted that Dr. Murphy testified as follows with respect to one of these procedures, column chromatography:

THE WITNESS: I would not regard column chromatography as a generally applicable recovery method. It is rarely, if ever, used in industrial practice for large scale use, and by recovery process I am referring to methods that are applicable on a large scale.

It can be used on a moderate scale to recover a few grams, maybe a hundred grams, but certainly not a commercial recovery process.

Pfizer has thus placed itself in the position of arguing that a procedure such as column chromatography which is capable of recovering a hundred grams of tetracycline would have been rejected by Lidoff as a sensitive analytical technique when its own Remarks and affidavits show that Lidoff was interested in the recovery from less than $\frac{1}{40}$ of a gram of antibiotic substance.

We also note that Pfizer attaches great significance to the fact that Bogert's affidavit told Lidoff that even if it be assumed that 10 percent of the potency of the amorphous product was due to tetracycline, the product could not contain more than 0.009 grams of tetracycline and he did not know of any method whereby he could separate and recover such a small quantity. This statement, however, as Lidoff pointed out, cannot be construed as an admission that coproduction of tetracycline actually occurred. Nor does it represent any sort of statement that tetracycline might have been coproduced in the *broths* in amounts up to 10 percent. And it is the *broths* which are significant here since Pfizer had actual knowledge that 5 percent of a Niedercorn broth consisted of tetracycline. There is no correlation between hypothetical percentages in amorphous materials and the *broths* from which they were taken, since the amorphous materials resulted from application of procedures that favored the recovery of tetracycline only. Even Hutz acknowledged this fact (Tr. 3767-73) and conceded that the interpretation which Pfizer now urges upon us is an invalid one:

Q. So, do you agree, then, that the supplemental affidavit did not tell the Patent Office Examiner that ten percent of the antibiotic product produced in *broths* 1771A and 1771B was tetracycline?

A. I do not think it stated that.

Q. It did not state that, did it?

A. I don't think so (Tr. 3777).

The reference in the supplemental affidavit to 10 percent of one particular amorphous product in no way can be construed as showing that Lidoff was not interested in amounts below 10 percent where tetracycline was clearly identified. If the quantity of amorphous material in question (having a potency of 260 micrograms per milligram) had been small enough, Bogert could have truthfully told Lidoff that assuming the maximum possible proportion of the total potency due to tetracycline is 50% or 75% or more, this means that the material contains less than 0.009 grams of tetracycline and that such a minute amount cannot be recovered in clearly identifiable form. This would certainly not indicate that Lidoff was not interested in the coproduction of tetracycline in these percentages.

Pfizer also contends that Lidoff frequently changed position with respect to the patentability of tetracycline and that he therefore had no firm view of the law on which he based his rejection of the Conover patent application. Consequently, it claims that Lidoff's testimony is entitled to no weight since Lidoff

admitted that it was based on a reconstruction of his views of "the principles of patentability."

The record reveals, however, that Lidoff changed his mind only as to the facts and not as to the principle of law involved. His rulings were changed solely on the basis of factual information supplied by respondents and are consistent therewith as noted in the Commission's first decision in this case (Opinion, pp. 36-38 [63 F.T.C. 1747,1834-1836]). For example, Lidoff's ruling that tetracycline hydrochloride was patentably distinguishable from tetracycline (referred to on page 8 of Pfizer's main brief) was made after an affidavit had been filed by a Bristol scientist in connection with the Heinemann application stating that tetracycline salts (such as tetracycline hydrochloride) had unexpected qualities over the free base, tetracycline, and therefore was patentably distinct. There is not one shred of evidence in the record, however, nor any indication whatsoever in any of Lidoff's rulings which would suggest that Lidoff would at any time have held tetracycline to be patentable had he known for sure of the presence of that antibiotic in prior art fermentations.

Pfizer next contends that Lidoff's reconstructed view of the law as to patentability of a chemical compound is contrary to the overwhelming weight of authority.¹² Therefore, according to Pfizer, it is highly improbable that Lidoff held such a view in 1954. This argument is also rejected. Lidoff's testimony that he considered the mere presence of tetracycline in prior art fermentations sufficient to anticipate tetracycline product claims is fully corroborated by his own written rejection of such claims and is perfectly consistent with Hutz's Remarks. Lidoff testified:

* * * In this record, I rejected the product claims then before me on the ground that the product was not novel because of a speculation, based upon another application, a Minieri application. This Minieri application indicated that tetracycline was co-produced in the production of chlortetracycline, or aureomycin. * * * I was able to base a speculation on the disclosure there that tetracycline was co-produced.

¹² Pfizer claims in this connection that there are numerous patent decisions that conflict with the position taken by Lidoff. We note, however, that the Board of Appeals in the Patent Office has subsequently, on at least one occasion, interpreted the law as Lidoff did. In so doing it distinguished decisions cited to us by Pfizer. See *Ex parte Steelmand & Kelly*, 140 U.S.P.Q. 189 (1962), a decision in which Mr. Lidoff participated as a member of the Board. This case and others cited therein hold that for a product to be patentable it must be novel, the only exception being where the claimed product possesses a utility that is different in *kind* from the prior-art product, and not merely in purity or degree. In the instant case, although Conover was entitled to claims on his deschlorination process for making tetracycline, he was not entitled to claims on the compound tetracycline if, as Lidoff pointed out, tetracycline had always been present in a mixture already known and used as an antibiotic. Were the rule otherwise, patent monopolies would be extended beyond the 17-year statutory period by successive discoveries of allegedly "new" antibiotic compounds which in reality were always present in known antibiotic products and processes although up until then unidentified.

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Based on this speculation, I rejected the product claims in this application [Conover] on the ground that the compound was not novel. And I might point out now, to stave off some future questions, that it was my opinion then, that if the compound * * * were not novel—if it existed, a patent could not validly issue. And I was interested in identification of that particular compound in the broths of the reference patents (Tr. 11,496-97).

He stated in his written rejection of the tetracycline product claims:

Minieri et al clearly and specifically disclosed 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.

And according to Hutz's Remarks, Lidoff had ruled that a "wholly unrecognized occurrence of some ineffective amount of tetracycline in a prior art product" would bar Pfizer's tetracycline product claims.

Pfizer's next argument concerns the failure of counsel supporting the complaint to call another patent examiner as a witness. Lidoff testified that at the time he was examining the Conover application he had no experience in the fermentation field; that applications dealing with fermentation processes were handled in another division (Division 63) by another examiner, a Mrs. Wendt.¹³ He further testified that it was standard Patent Office procedure at the time for an examiner who was unfamiliar with the subject matter of an application to rely on informal memoranda, known as patentability reports, prepared by an experienced examiner, and that his rejections of tetracycline process claims were based on memoranda written by Mrs. Wendt.¹⁴ Since it appears that Mrs. Wendt was available as a witness during the trial of this case, Pfizer contends that it may be inferred from complaint counsel's failure to call her that her testimony would have been damaging to the Commission's case. Pfizer's counsel further state that they "did not know of Mrs. Wendt's significant role" until the hearing on remand and claim therefore that they were under no obligation to call her.

We note first of all that the statement by Pfizer's counsel that

¹³ Lidoff's division, Division 6, was assigned the Conover application because under Patent Office procedures at the time, applications such as Conover's, which contained product claims, were assigned to Division 6 (Tr. 9460).

¹⁴ Lidoff testified, however, that no complications arose from this fact (Tr. 11,544). He alone made the decision to apply the doctrine of inherent production to Conover's *product* claims.

they did not know of Mrs. Wendt's involvement in this matter until the remand hearing, is untrue. The record shows that on December 2, 1959, Dr. Herbert W. Taylor testified at length concerning the patentability report procedure and as to the connection between Division 6 (Mr. Lidoff's division) and Division 63 (Mrs. Wendt's division). After he mentioned Mrs. Wendt by name, the following colloquy took place between Bristol's counsel and Dr. Taylor: (Tr. 9462)

Q. Who was Mrs. Wendt—

A. The examiner in Division 63 who handled all of these other applications that Bristol filed that went to 63. I was told by her that she'd written the section of Lidoff's decision on motions which we have focused our attention on, that is the inherent production rejection.

Q. You mean the decision of October 14, 1954, in the second interference proceeding?

A. I do.

Secondly, we note that Pfizer's argument ignores other evidence of record which completely rebuts any inference unfavorable to the complaint which may possibly be created by complaint counsel's failure to call Mrs. Wendt. The record shows, in this connection, that even after the Conover patent had been granted, Mrs. Wendt rejected a Pfizer application for a patent on a process for making tetracycline (Tanner, et al.). And the reason given by Mrs. Wendt for rejecting this application was coproduction of tetracycline by prior art processes. In a rejection dated October 4, 1956, Mrs. Wendt specifically stated "Claims 1 to 4 are again rejected as lacking invention over each of Duggar and Niedercorn, of record, for reasons set forth in the record. * * * The processes of patentees [Duggar and Niedercorn] produced tetracycline as well as chlortetracycline, as evidenced by each of Bird and Martin [references cited by Mrs. Wendt]. It is immaterial whether or not this concomitant production was recognized or not as note *Allen et al., v. Coe* * * * " ¹⁵ The record further shows that Mrs. Wendt again rejected the Tanner application on April 23, 1957, and again on June 6, 1958, specifically holding that "All the claims are again rejected as lacking invention over each of Duggar, Niedercorn of record, for reasons fully dismissed [sic] therein and Minieri, newly cited, who discloses the production of tetracycline by members of the same genus as that employed by applicant" (CX 921).

In view of the above rejections by Mrs. Wendt and her insistence

¹⁵ (CX 921) One of the references cited by Mrs. Wendt, *Bird, et al., Antibiotics and Chemotherapy*, dated August 7, 1954 (CX 896) described a procedure for separating tetracycline, chlortetracycline, and oxytetracycline by means of paper chromatography.

that tetracycline was inherently produced by Duggar and Niedercorn despite Pfizer's "proof" in the Conover matter (which was cited to her) that it was not, we do not believe that Mrs. Wendt's testimony would have been favorable to Pfizer had she been called as a witness.

Pfizer also argues that the record is "crystal clear that Lidoff was thoroughly acquainted with the phenomenon of tetracycline coproduction at the time of the interviews with Hutz and Murphy" and that this evidence contradicts Lidoff's testimony that he did not believe that he then knew of "any coproduction." In support of this argument Pfizer refers to statements in various patent applications which disclosed coproduction of tetracycline and Aureomycin and to certain of Lidoff's rulings rejecting tetracycline process applications on the basis of his speculation that tetracycline was coproduced by the Duggar and Niedercorn processes. The short answer to this argument is that Lidoff did not testify that he was unaware of "any coproduction." He testified only that he was unaware that tetracycline was coproduced by prior art processes, *i.e.*, by Duggar or Niedercorn. Lidoff was, of course, informed by applications, such as Minieri, which were before him at the time, that the processes disclosed therein produced tetracycline concomitantly with Aureomycin. But these applications covered *new* processes utilizing *newly* developed strains of *S. aureofaciens* or conditions of fermentation which were different from those disclosed in Duggar or Niedercorn. It was on the basis of the information contained in these applications that Lidoff speculated that tetracycline was coproduced by the *prior art* processes. And in Lidoff's view coproduction of tetracycline would anticipate Conover's claims only if it occurred in the prior art.

The significance of coproduction of tetracycline by prior art processes, as distinguished from coproduction by later developed processes, is pointed up most clearly in the following arguments made to Lidoff by Hutz:

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 (CX 4, pp. 34-35).

We note that in the above argument Hutz told Lidoff that the Minieri brief stated that "there is no evidence of inherent production by the prior art processes." Pfizer's counsel now argues to the Commission that the same Minieri brief contains "positive proof" of coproduction that Lidoff could have used to reject Pfizer's claims if he was interested in the coproduction of useless amounts of tetracycline. In this instance, however, we agree with Hutz. The Minieri brief did not inform Lidoff of coproduction in the prior art.

Another aspect of this argument which must be noted concerns Pfizer's counsel's reliance on the following statement by Lidoff in his rejection of the Bogert et al. application on November 2, 1954, as proof of Lidoff's knowledge of coproduction:

Claims 1 to 6 are rejected as being unpatentable over Winterbottom et al. who treats crude chlortetracycline (Aureomycin) compounds produced by the process of the Duggar patent which must, inherently, include some tetracycline, * * *. Since tetracycline would be an "impurity" in the crude chlortetracycline employed, applicants process would inherently [be] performed * * *.

According to Pfizer this statement shows that Lidoff believed that tetracycline was an impurity in the prior art and it further argues that he was correct in this belief. Yet the record shows that Pfizer's officials had furnished Lidoff with information which caused him to change his mind. Subsequent to the submission of affidavits in the Conover application, the following representation was made to Lidoff in a document signed by Connolly and Hutz:

It is believed that the Patent Office is now aware of the fact that this "inherent" production of tetracycline by the Duggar process is not in fact true. Tetracycline would most emphatically not be an "impurity" in the prior art methods, as the Examiner believed at the time of his last Office Action herein, * * * (CX 13, p. 16).

Under the circumstances, it is obvious that the Pfizer attorneys construed the affidavits as proof that no identifiable tetracycline was coproduced in the prior art.

Pfizer next contends that even if it be assumed that Lidoff was interested in the coproduction of any identifiable tetracycline, he was careless in reviewing Hutz's Remarks and ignorant of fermentation processes; and that as a result he misled Pfizer's representatives regarding the information he wanted. In the first place, we find no basis in the record for the charge that Lidoff was careless. As we have noted before, Pfizer's summary of what transpired at the conferences was sufficiently in accord with Lidoff's position that he had no reason to question the written

account of these conferences. Further, even though Lidoff, as he testified, was unfamiliar with fermentation processes this cannot condone Pfizer's withholding of relevant data. On the contrary, in the face of these circumstances, Pfizer's representatives and scientists, being the experts on fermentation processes, were under a still greater duty to be zealous in providing Lidoff with the information they had in their possession.

Aside from these unfounded charges, Pfizer bases the assertion that Lidoff failed to communicate his thoughts on the following portion of his testimony (Tr. 11,601-602) :

Q. Do you consider that Mr. Hutz and Mr. Murphy gave you what they understood you were interested in?

A. Do you want me to answer that question?

Q. Yes.

A. As far as I know, I assumed that they gave me what I had asked for, but they gave me what they understood, yes. They did not give me—well, I retract that. I don't know what they gave me with relation to what I actually wanted.

Q. But they gave you what they understood you wanted.

A. Apparently.

Q. Isn't that so?

A. Apparently so, I have no reason to believe otherwise.

Pfizer construes this testimony as an acknowledgement by Lidoff that Hutz and Murphy probably misunderstood him. We do not agree. The portion of the testimony immediately preceding the excerpt that Pfizer relies on reads as follows (Tr. 11,601) :

A. I have no control of what they understood by my words. Whatever they understood, my feeling was that this patent should not issue if the compounds were not novel. And this is the only thing that I was basing my stand on.

What they understood by my words I do not know and have no influence on at all.

Obviously, Lidoff realized that he could not testify as to what knowledge Pfizer's representatives possessed. His testimony cannot be invoked as support of Pfizer's professed innocence. It is a question for this tribunal to determine whether Pfizer has acted in accordance with the principles of utmost candor and good faith.

From our review of the record we find that Lidoff did communicate to Pfizer's officials the fact that he was interested in the presence of tetracycline in prior art fermentations. We base this finding on evidence already referred to herein and on the clear showing in the record that prior to the November 29 and December 8 interviews at the Patent Office the basis for Lidoff's rejection of the tetracycline claims was well known to other interested persons.

The record discloses beyond question that officials of Upjohn, Cyanamid, Squibb and Bristol knew that Lidoff had speculated that tetracycline has been inherently produced in the prior art and that the ground of his rejection of the tetracycline claims was lack of novelty. Contemporaneous statements of these officials reveal that they knew that Lidoff was interested solely in the fact of coproduction, that in his view the mere presence of tetracycline in the prior art would anticipate claims for the product.

We also find that even under Pfizer's view that Lidoff was interested solely in quantities of tetracycline that could be recovered by practical recovery procedures (as distinguished from smaller quantities that could be identified only by analytical methods), its representatives were guilty of suppressing material information. In selecting the prior art fermentations for their tests, Pfizer's representatives had a clear choice to make: whether to run a fermentation of Niedercorn Example 1, which Dr. Bogert already knew produced broths having significant antibiotic potency containing 5 percent tetracycline, or whether to test Example 28 which he knew consistently produced broths having little or no antibiotic potency and were useless for determining whether coproduction occurs. They chose the poorer example for their tests and suppressed the facts pertaining to Example 1. Dr. Bogert later testified that he could have recovered tetracycline from a Niedercorn Example 1 broth (CX 34, p. 32). The obligation to deal with the Patent Office in utmost good faith required Pfizer to place this information before Lidoff. Lidoff testified that had he been told of these facts at the November 29 conference, he would not have required any further tests of Pfizer but would have let his previous rejection stand.

Although Hutz and Murphy denied knowledge of the results of the prior October experiments of Tanner and Bogert in which Bogert found clear evidence of coproduction, nevertheless it was Porter, Pfizer's general counsel, and Murphy who had initiated those prior experiments in an effort to gather data to disprove Lidoff's speculation that coproduction occurred. Also, the record shows that Tanner had conveyed to Murphy some of the relevant data about those experiments, such as the troublesome high level of pH that Tanner encountered in running the Niedercorn Example 28 fermentation (Tr. 4227-29). But even if Hutz and Murphy did not know specifically of Bogert's identification of five percent tetracycline at the time of the first conference with Lidoff on November 29, 1954, the information was clearly available to them by the December 8 conference since they had worked side-by-side with

Bogert in the meantime. It is obvious that they were either told of Bogert's discovery of coproduction or he secreted it from them. In either case, the Patent Office was kept in the dark by deliberate withholding on the part of some Pfizer employee or employees.

In addition, material information was suppressed by Pfizer regarding both the extremely low potencies of the test broths ($\frac{1}{20}$ th of those described in the patents) and the fact that during the initial stages of fermentation of one of the broths the pH far exceeded the optimum limits prescribed by the Niedercorn patent. Although the low potencies and the high pH may not have been the fault of Pfizer's scientists it was obviously relevant information and Mr. Lidoff testified that had he known of these facts he would not have considered the tests as duplicating the prior art processes.

In dealing with the Patent Office, applicants can and do, of course, present favorable data to support their claims. But at the same time they can not in good faith withhold conflicting or unfavorable data. The Patent Office, not having testing facilities of its own, must rely upon the integrity of applicants and their attorneys. They stand to that Office in a confidential relationship and must observe "the highest degree of candor and good faith." *Kingsland v. Dorsey*, 338 U.S. 318,319 (1949). "Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies." *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806,818 (1945).

The Commission in its first decision in this matter, without the benefit of the patent examiner's testimony, based its opinion on the finding that Pfizer's actions, at the very least, amounted to "unclean hands," "inequitableness" and "bad faith"—the grounds which strip a patentee of his rights to enjoin infringement of his patent in a court of equity. See *Precision Instrument, supra*, and *Hazel-Atlas Co. v. Hartford-Empire Co.*, 322 U.S. 328 (1944). Mr. Lidoff's testimony has fully corroborated that finding, and on the basis of our examination of the entire record we conclude that Pfizer failed to abide by the standards of candor and good faith in procuring its patent, and that this conduct together with the subsequent exploitation of the tetracycline patent constituted a violation of Section 5 of the Federal Trade Commission Act. As a result of this offense, Pfizer has been able to exercise monopoly rights over an important antibiotic, sales of which have exceeded \$100 million per year.

We further find, as an alternative ground, that the evidence is clear and convincing that Pfizer committed fraud upon the Patent

Office in procuring its patent. Pfizer's subsequent attempt to monopolize the tetracycline market was a violation of Section 2 of the Sherman Act, *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), and hence of Section 5 of the Federal Trade Commission Act.

Cyanamid's Appeal

As stated above, in November 1953, Lidoff asked Harvey Edelblute, Cyanamid's patent counsel, whether strains of *S. aureofaciens* used by Cyanamid in producing Aureomycin may have produced tetracycline. Edelblute assured Lidoff in December 1953 that Cyanamid had never produced any tetracycline "inadvertently or otherwise" in prior Aureomycin operations. Subsequently, however, Cyanamid determined the presence of tetracycline in Aureomycin products but failed to divulge this information to the Patent Office.

The examiner found that not only did Edelblute fail to inform Lidoff of the true facts when they became known to him but that "while the second interference was in progress, Cyanamid's representative, in papers filed with the Patent Office, continued to deny any inherent production," Mr. Lipscomb further held that had Cyanamid advised the patent examiner during the second interference that the Duggar and Niedercorn fermentations contained tetracycline and that commercial Aureomycin contained tetracycline, the Pfizer-Conover patent application would have been barred because (1) tetracycline was produced under the processes of prior patents and (2) tetracycline was available to the public prior to the filing of the Conover application.

Cyanamid argues that Edelblute did not know the real basis for Lidoff's rejection of the tetracycline claims, that Edelblute had no knowledge of coproduction of tetracycline in the manufacture of Aureomycin, and that even if Edelblute knew that tetracycline was coproduced with Aureomycin, such information would have had no bearing whatsoever on the issue of whether tetracycline was patentable under Lidoff's view of the law.¹⁶

None of these contentions has merit. As to Edelblute's under-

¹⁶ We are also asked to dismiss the complaint as to Cyanamid on the ground of mootness since its principal Aureomycin patent, i.e., the Duggar patent, expired in 1966. The Niedercorn patent, however, which was issued as an "improvement" patent on the Duggar patented process, will not expire until 1969; and under the Commission's original order in this case Cyanamid was required to license not only the Duggar patent but also the Niedercorn patent. We have no assurance that Cyanamid might not seek to employ the Niedercorn patent in an attempt to enjoin the utilization of tetracycline fermentation processes as this respondent has done with respect to the Duggar patent. Furthermore, the disclosure of certain technological know-how required by the Commission's original order has not been rendered moot by the expiration of the Duggar patent.

standing of Lidoff's view of patentability and hence his interest in coproduction of tetracycline, Cyanamid contends that even if Edelblute "had known that actually small amounts of tetracycline were produced in making Aureomycin he still would not have thought Lidoff would regard this as barring patentability to tetracycline." According to Cyanamid, Edelblute thought that "Lidoff wanted to know whether substantial amounts of tetracycline were produced by prior art processes, or were present in Aureomycin, to have the utility of tetracycline unmixed with chlortetracycline." In making this argument Cyanamid completely ignores evidence which establishes beyond any reasonable doubt that Edelblute knew that Lidoff regarded the mere presence of tetracycline in the prior art product as sufficient to bar patentability to tetracycline. This evidence includes a memorandum written by Edelblute on October 27, 1954, wherein he commented on Lidoff's October 14 ruling that tetracycline was unpatentable because of inherent production. Referring to this ruling by Lidoff, Edelblute stated: " * * * 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." (RACX 878C.) It is obvious from this statement that Edelblute did not believe that Lidoff was interested only in whether substantial amounts of tetracycline were coproduced.

The record also discloses that Edelblute was informed prior to the dissolution of the second interference that tetracycline was coproduced with Aureomycin. On February 25, 1954, Dr. Nestor Bohonos, The Cyanamid Director of Mycology Research, sent the following memorandum on the subject of "Old Aureomycin Samples for Chromatographic Study" to Dr. 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 111B).

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."

With respect to Cyanamid's argument that information concerning the coproduction of tetracycline in the manufacture of Aureomycin would have been of no interest to Lidoff, the record shows that one of the principal arguments made to Lidoff by Pfizer in support of its position that tetracycline was not coproduced by the Duggar and Niedercorn processes was that Cyanamid "who manufactured literally tons of chlortetracycline (Aureomycin) * * * 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."

Not only was the information in question relevant to the issue of patentability under Lidoff's view of the law but Edelblute, by Cyanamid's own admission, knew it was false when he reviewed the Conover file in January 1955. Edelblute nevertheless characterized Pfizer's prosecution of the Conover application as "straight-forward" and could see no evidence of "falsification of facts" (RACX 880).

Cyanamid argues that Lidoff was never asked to testify as to whether or not he relied on any of Edelblute's statements when he allowed Pfizer's patent application. Lidoff did testify, however, that had Cyanamid disclosed the fact that tetracycline was present in Aureomycin, he would have used the information in rejecting Pfizer's application on the additional ground that tetracycline was part of a product that had been in public use and sale. See 35 U.S.C. 102(a) and (b). Of course, as Lidoff explained, in order to use such information against Pfizer, under Patent Office rules the information had to be in a form accessible to Pfizer. Disclosure in connection with the Minieri application at the time that Edelblute was informed of the fact of coproduction in February 1954 would have made the information available to Pfizer during the second interference and would have allowed Lidoff to use the information in rejecting Pfizer's claims.

The only remaining question is whether Cyanamid was under a duty to make such disclosure in Minieri. We find that Cyanamid was, since it was pressing for both tetracycline product and process claims in Minieri and knew that Lidoff believed that coproduction was relevant to the validity of such claims. Cyanamid also knew that Lidoff had been incorrectly informed by Edelblute that coproduction did not occur.

Edelblute himself apparently realized that he was obliged to correct the record in the Minieri application because later he did file a paper in Minieri in which he stated "Reinvestigation of retention samples of commercial Aureomycin produced by

applicant's assignee [Cyanamid] by the Duggar and Niedercorn processes showed that these materials contained amounts of tetracycline ranging from 1 to 2½ percent of tetracycline as against chlortetracycline of these products" (CX 8, p. 82). Conveniently for Pfizer and Cyanamid, however, the disclosure was not made until after the Conover patent had issued to Pfizer. At that point it was too late for the Patent Office to act since once a patent is issued the Office has no authority to recall it.

In sum, the evidence is clear and convincing that Cyanamid deliberately withheld from the Patent Office information which it knew or had reason to believe was relevant to the validity of Pfizer's application for a patent on tetracycline. Cyanamid pursued this course of action with knowledge that it was assured a license in the event a patent on tetracycline issued to Pfizer, and that its position as a leading producer of broad-spectrum antibiotics would be safeguarded because Pfizer had announced its intention that Cyanamid would be the *sole* licensee under any patent that issued. Cyanamid's vital interest in seeing a patent on tetracycline issue—preferably to itself, or at least to Pfizer—is vividly illustrated by a statement made by Edelblute to the Patent Office. In urging an early dissolution of the second interference, even though the result might be immediate issuance of a patent to Pfizer, Edelblute explained 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). Although Bristol, Squibb, and Upjohn were eventually able to force their way into the licensing arrangement by threatening to contest the validity of the Conover patent, Cyanamid continued to outsell all others by virtue of the lead time it had gained in establishing "Achromycin" as the brand name for its tetracycline product.

Conclusions as to the Patent Aspect of the Case

After considering the appeals of respondents Pfizer and Cyanamid from Hearing Examiner Lipscomb's initial decision and after reexamination of the entire record in this proceeding, the Commission has determined that the hearing examiner's findings and conclusions as supplemented by this opinion, should be adopted and the appeals denied. Also adopted are findings 1 through 18 and 27 through 29 entered by the Commission on August 8, 1963. Allegations in the complaint, other than those dealt with specifically in the opinion, are dismissed in accordance with the reasoning set forth in the Commission's opinion of August 8, 1963.

The Price-Fixing Charge

In its first decision, the Commission found that respondents had unlawfully agreed to hold the price of tetracycline at the same level as that maintained for the other so-called broad-spectrum antibiotics since 1951. The Commission entered an order on August 8, 1963, requiring respondents to cease and desist from future price fixing and directed them to establish, independently, new prices for their respective tetracycline products.

Subsequent to the Commission's order of December 17, 1963, which directed Pfizer and Cyanamid to license any qualified applicant under their respective patents for the manufacture or sale of tetracycline, new firms entered the field, although not licensed by Pfizer and Cyanamid. *American Cyanamid Company v. Federal Trade Commission*, 363 F. 2d 757, 817; *McKesson & Robbins, Inc. v. Chas. Pfizer & Co., Inc. and American Cyanamid Co.*, 235 F. Supp. 743 (E.D. Pa. 1964). And while the evidence in the record is limited to the period prior to July 28, 1958, current reports indicate that the price of tetracycline has declined substantially.

Pfizer represents in its brief that bid prices to hospitals have moved downward to levels of less than one-fourth of the 1958 bid prices and that list prices in the prescription market have also fallen. According to this respondent, the price to the retailer of one bottle of 100 capsules (250 mg.), which the record shows was \$30.60 in 1958, is now listed by Cyanamid at \$11.22, and other competitors of Pfizer sell at even lower "effective" prices. In the face of these developments, it is not unreasonable to assume that prices will tend to be still more competitive once the Commission's licensing order goes into effect.

Mindful that the goal of its order is to remove unlawful restraints and foster future competitive conditions rather than punish for past conduct, two of the four participating members of the Commission (Commissioners Reilly and Elman) believe that the public interest will be adequately served by compulsory licensing and by continued close scrutiny of Pfizer's and Cyanamid's readiness to license others to make and sell tetracycline. In the view of these members, it is now unnecessary to decide whether the uniformity of prices in the 1950's was the result of a price-fixing conspiracy as contended by complaint counsel or the product of conscious parallelism as respondents seem to suggest. On the other hand, the other two participating members of the Commission (Commissioners MacIntyre and Jones) believe that the evidence of record amply substantiates the allegations in the

complaint relating to price fixing. In the view of these two members, the Commission should adhere to and renew the findings of fact and conclusions of law, and issue the order to cease and desist, relating to the price fixing phase of the case, which were contained in the Commission's previous decision of August 8, 1963. Since there is not a majority of the participating Commissioners favoring such action, however, the portion of the complaint which charges respondents with fixing prices must be dismissed.

The Order

In its original order of December 17, 1963, in this matter, the Commission directed Pfizer to license its Conover patent and so remove the fetters on the manufacture and sale of tetracycline by qualified domestic firms provided they pay Pfizer a 2½ percent royalty on their "net sales." The order included a similar provision with respect to Cyanamid, requiring that respondent to license two Aureomycin patents, *i.e.*, Duggar and Niedercorn, in the event a licensee sought to use Aureomycin or patented Aureomycin processes in the manufacture of tetracycline. Both companies were to provide certain technological information to licensees.

Complaint counsel urge us to eliminate from the new order, which is being issued together with our opinion, the provision calling for the payment of royalties. The asserted basis for this request is the fraud committed by Pfizer and Cyanamid before the Patent Office. But we see no reason to depart from the Commission's first order in this respect. In the opinion accompanying that order, which we adopt, the Commission viewed the proceeding as "antitrust" in nature, and the goal of the order was to eliminate the patent barrier which blocked entry into the tetracycline market, thus prying open the market to newcomers. As the Commission found in its first opinion, a royalty-bearing licensing arrangement may suffice as a means to create and maintain competition in the tetracycline market. Should the provision for a royalty ever become an impediment to effective competition, we can always reopen the matter and eliminate the royalty or modify the rate as changed conditions may require.

We have no doubt that, where the circumstances justify such relief, the Commission has the authority to require royalty-free licensing. See Note, *Improperly Procured Patents: FTC Jurisdiction and Remedial Power*, 77 Harv. L. Rev. 1505, 1517-19 (1964). Indeed, were this to be considered a *de novo* question in this case, we might well agree with the dissenting Commissioner on the desirability of such a provision here, particularly on the basis of

the evidence adduced at the hearing on remand. But, in view of the history of this litigation and particularly in light of the matters settled in the opinion of the Court of Appeals, we think it would be a serious mistake to inject so controversial a new issue into the case at this stage, delaying and perhaps jeopardizing its ultimate disposition.

DISSENTING STATEMENT

SEPTEMBER 29, 1967

BY JONES, *Commissioner*:

In this decision on remand, the Commission has found unanimously that the tetracycline patent issued to Pfizer was procured by fraud on the part of Pfizer and by deliberate misrepresentation and withholding of essential and relevant data relating to the patentability of tetracycline on the part of both Pfizer and Cyanamid. The Commission concluded that Pfizer's conduct (which Cyanamid deliberately assisted) "in procuring its patent * * * together with the subsequent exploitation of the tetracycline patent constituted a violation of Section 5 of the Federal Trade Commission Act." Thus the Commission's opinion makes plain that it is the procurement of the patent which is the gravamen of the wrong committed by respondents here followed by the monopolization conduct which that wrongfully procured patent permitted.

I join in the Commission's opinion on the liability of these respondents as respects the wrongful procurement of the patent. I vigorously dissent from that portion of the order entered here by the Commission which expressly permits these respondents to collect royalties under the patents which the Commission found were wrongfully procured and exploited by them.¹ There is absolutely no basis either in logic, reason, equity, fact, or law for this decision on the part of the majority.

The Commission defends its action in this respect by pointing to the fact that the order is designed "to eliminate the patent barrier which blocked entry into the tetracycline market thus prying open the market," that a royalty-bearing licensing arrangement "consti-

¹ The Commission's order directs compulsory licensing of Pfizer's tetracycline patent and also of Cyanamid's Niedercorn patent to the extent that it is used for the production of tetracycline. The Commission's theory, with which I am in complete agreement, is that both these patents are involved in the production of tetracycline. Cyanamid's deliberate withholding of information from the Patent Office with respect to the validity of Pfizer's application for a patent on tetracycline amply justifies the need for the same relief with respect to its patent to the extent that it too constitutes a barrier to the manufacture of tetracycline as the Commission ordered with respect to Pfizer's patent. It is in this sense that I refer in this dissent to these patents conjointly in the plural and describe them as "wrongfully procured and exploited" by respondents.

tutes a fair means to create and maintain competition in the market" and thus accomplishes this objective. I do not agree that the objectives of antitrust orders are so narrowly confined. Clearly the objective of a Federal Trade Commission proceeding charging respondents with engaging in unfair methods of competition whose effect was to eliminate competition in the sale of tetracycline must be to restore the competition which respondents' conduct has eliminated. Removing barriers to entry in a market achieves only one aspect of this objective. If the new entrants come into the market with one hand tied behind their backs, the mere opening of the market to them is a vain and futile gesture. The importance of licensing fees in "limiting or inhibiting the growth of competition" was pointed out by the Court in *United States v. General Electric*, 115 F. Supp. 835, 844 (D.N.J. 1953).

Pfizer stated in its brief that price competition is today of great importance in the tetracycline market and that they expect that it will greatly intensify after the Commission's licensing order goes into effect (Pfizer's Answering Brief Opposing Royalty-Free Licensing, pp. 8-9). Thus Pfizer admits that the major competition in the tetracycline market in the future will be price competition. Indeed the two Commissioners who refused to find that a price-fixing order was necessary here did so on the very ground that substantial price competition had been introduced into this market and that, therefore, no price-fixing order was necessary in this case. If these assumptions with respect to price competition are valid, then the majority's order permitting respondents to collect 2½ percent royalties from their competitors under patents which this Commission unanimously finds were wrongfully procured and wrongfully exploited confers on these respondents what could amount to a decisive competitive edge price wise over all of their competitors. Under the Commission's order these competitors of respondents who have been wrongfully excluded from the market all these years must now come to respondents for a license for which they must pay a substantial royalty and thus the order in essence permits respondents to maintain competitive advantages unlawfully achieved (the very monopolistic conduct which this Commission has just found to be a violation of Section 5).

I cannot agree that this provision in the majority's order requiring respondents' competitors to pay tribute under patents which were wrongfully procured and exploited "constitutes a fair means to create and maintain competition in the market."

Nor do I read any of the case law on this point as precluding either the Commission or a court from prohibiting a respondent

from collecting license fees under the circumstances of the facts which we have found in this case.² Indeed the Supreme Court in its decision in *United States v. National Lead Co.*, 332 U.S. 319, 349 (1947) expressly contemplated the propriety of such ruling in the proper circumstances when it concluded in that case that "On the facts before us, neither the issuance of such licenses on a royalty-free basis nor the issuance of a permanent injunction prohibiting the patentees and licensees from enforcing those patents has been shown to be necessary in order to enforce effectively the Antitrust Act."³ In *United States v. General Electric*, 115 F. Supp. 835, 844 (D.N.J. 1953) the Court did in fact sustain the propriety of precisely this type of relief because the importance of price competition and the narrow profit margins prevailing in the lamp industry made it essential to deprive GE of the competitive advantage which collection of the licensing fees would confer on it.

To me the only relief which can be effective and which carries any hope of opening up this market to genuine fair competition and undo the harm to competition which these respondents' conduct has engendered is to enjoin their collection of royalties under these patents in view of the circumstances of their issuance and respondents' exploitation of them. Such an injunction is not an adjudication of the ultimate patentability of tetracycline nor does it operate as a forfeiture of either patent. It simply effectuates the purport of the Commission's decision to the effect that the tetracycline patent, as well as Cyanamid's Neidercorn patent when used to make tetracycline, cannot be exploited because of the wrongful conduct of respondents in procuring the tetracycline patent. Interested parties are left to whatever remedies are available to them, either to seek cancellation of the tetracycline patent or if possible, to perfect the issuance of the tetracycline patent on the basis of a full disclosure of all relevant facts. In the latter event, this order

² The Sixth Circuit in its opinion on appeal in this case (*American Cyanamid Company v. F.T.C.*, 363 F. 2d 757, 772 (1966)) stated that it was not holding that the Commission could order compulsory royalty-free licensing. I do not believe that this statement can be read as respondents would have us read it as laying down a guide-line or establishing the case law for our decision. We must interpret the Sixth Circuit's opinion in terms of the issues before the Court and in the light of the applicable case law on the point laid down by the Supreme Court.

³ The Supreme Court's opinion in *Hartford Empire Co. v. United States*, 323 U.S. 386 (1945) furnishes no support for respondents' arguments to the contrary. There, the illegal conduct with which the Court was concerned involved patent pooling and allocation of markets and did not embrace the type of fraud and misrepresentation vis-a-vis the Patent Office in procuring the patent which is the sole basis for the wrong found here. The Supreme Court stated expressly that " * * * if, as we must assume on this record, a defendant owns valid patents, it is difficult to say that, however much in the past such defendant has abused the rights thereby conferred it must now dedicate them to the public" (p. 415).

could be reopened and modified if it could be shown that any of its terms were no longer warranted under the circumstances.

FINAL ORDER

This matter having been heard by the Commission upon the cross-appeals of respondents Chas. Pfizer & Co., Inc., and American Cyanamid Company and counsel supporting the complaint from the hearing examiner's initial decision following the remand of the case by the United States Court of Appeals for the Sixth Circuit and upon the appeal of counsel supporting the complaint from the original initial decision in this matter issued October 31, 1961; and

The Commission having determined for the reasons stated in the accompanying opinion that the appeals of respondents and counsel supporting the complaint should be denied:

It is ordered, That the original initial decision in this matter issued October 31, 1961, be, and it hereby is, vacated and set aside;

It is further ordered, That the findings and conclusions contained in the initial decision following remand be, and they hereby are, adopted as the findings and conclusions of the Commission as supplemented by (1) the accompanying opinion of the Commission, (2) findings 1 through 18 and 27 through 29 contained in the Commission's Findings as to the Facts and Conclusions of Law issued August 8, 1963 [63 F.T.C., 1747 at 1755-1771, 1781-1784] and (3) Part II of the Commission's Opinion accompanying the Final Order issued December 17, 1963 [63 F.T.C. 1747, 1901].

It is further ordered, That respondent Chas. Pfizer & Co., Inc., grant to any domestic applicant making written request therefor, a nonexclusive, nondiscriminatory license to make, use, and sell tetracycline under all claims of United States Patent 2,699,054. Said licenses granted hereunder shall be for the full, unexpired term of said patent and shall contain no restriction or limitation, except that such licenses may contain provisions in a form customary in such patent licenses, allowing the licensor to collect royalties of not more than two and one-half (2½) percent of the net sales of tetracycline manufactured or sold under said licenses, providing for the inspection of books and records by independent auditors to determine the correctness of any royalty payment, and providing for the cancellation of the licenses at the option of the licensor upon failure of the licensee to permit such inspection or to pay royalties due and payable. Said licenses shall provide that in the case of the licensor granting or having granted more favorable terms to any other licensee, the licensee under said license shall be entitled to

equal treatment: *Provided, however,* That respondent may require any such applicant to pay upon acceptance of a license an amount not exceeding \$2,500 which shall be applied against future royalty payments.

It is further ordered, That respondent American Cyanamid Company grant to any domestic applicant making written request therefor, a nonexclusive, nondiscriminatory license under all claims of United States Patent 2,609,329. Said licenses granted hereunder shall be for the full, unexpired term of the patent licensed and shall contain no restriction or limitation on the licensee's right to make and sell tetracycline, except that such licenses may contain provisions, in a form customary in such patent licenses, allowing the licensor to collect royalties of not more than two and one-half ($2\frac{1}{2}$) percent of the net sales of tetracycline manufactured under said licenses, providing for the inspection of books and records by independent auditors to determine the correctness of any royalty payment, and providing for the cancellation of the licenses at the option of the licensor upon failure of the licensee to permit such inspection or to pay royalties due and payable. Said licenses shall provide that in the case of the licensor granting or having granted more favorable terms to any other licensee, the licensee under said license shall be entitled to equal treatment: *Provided, however,* That respondent may require any such applicant to pay an amount not exceeding \$2,500 which shall apply against future royalty payments under any patent or patents licensed hereunder.

It is further ordered, That respondents Chas. Pfizer & Co., Inc., and American Cyanamid Company each refrain from making any assignment, sale, or other disposition of any of the patents required to be licensed hereunder which would deprive it of the power to issue licenses pursuant to this order unless said respondent requires as a condition of such disposition that the purchaser, assignee, or licensee shall observe the provisions of this order with respect to such patent and that the purchaser, assignee, or licensee file with the Commission a written undertaking to be bound by such provisions: *Provided, however,* That one or both of said respondents may dedicate any such patent, patents, or a general patent license to the general public in lieu of issuing licenses pursuant to the provisions of this order.

It is further ordered, That respondent American Cyanamid Company furnish to any person licensed under this order, and making written request therefor, whatever technical information and know-how that American Cyanamid Company has in the past

furnished Chas. Pfizer & Co., Inc., relating to the manufacture and use of chlortetracycline, said technical information and know-how to include a furnishing of viable *S. aureofaciens* cultures that are identical to or equivalent to any cultures furnished Chas. Pfizer & Co., Inc. The information to be made available hereunder shall be made available without charge other than the expense to respondent of furnishing such information: *Provided, however*, That respondent American Cyanamid Company may require any such licensee to agree to keep said technical information and know-how confidential.

It is further ordered, That respondent Chas. Pfizer & Co., Inc., furnish to any person licensed under United States Patent 2,699,054 pursuant to this order, and making written request therefor, whatever technical information and know-how that Chas. Pfizer & Co., Inc., has in the past furnished American Cyanamid Company relating to the manufacture of tetracycline by the deschlorination process. The information to be made available hereunder shall be made available without charge other than the expense to respondent of furnishing such information: *Provided, however*, That respondent Chas. Pfizer & Co., Inc., may require any such licensee to agree to keep said technical information and know-how confidential.

It is further ordered, That respondents American Cyanamid Company and Chas. Pfizer & Co., Inc., shall within sixty (60) days after the effective date of this order file with the Commission a written description of the know-how and technical information required to be furnished under Paragraphs 6 and 7.

It is further ordered, That that portion of the complaint charging respondents with fixing prices be, and it hereby is, dismissed.

It is further ordered, That respondents American Cyanamid Company and Chas. Pfizer & Co., Inc., each shall file with the Commission within sixty (60) days after the effective date of this order, a report in writing under oath, signed by each respondent, setting forth in detail the manner and form of its compliance with this order.

Chairman Dixon not participating; and Commissioner Jones dissenting from that portion of the order permitting respondents to collect royalties under the patents.

IN THE MATTER OF

I. SPIEWAK & SONS, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO THE ALLEGED VIOLATION OF THE
FEDERAL TRADE COMMISSION AND THE WOOL PRODUCTS LABELING
ACTS*Docket C-1258. Complaint, Sept. 29, 1967—Decision, Sept. 29, 1967*

Consent order requiring a New York City clothing manufacturer to cease misbranding its wool products and failing to affix proper labels thereto.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and the Wool Products Labeling Act of 1939, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission, having reason to believe that I. Spiewak & Sons, Inc., a corporation, and Gerald Spiewak, Robert I. Spiewak and Martin H. Spiewak, individually and as officers of said corporation, hereinafter referred to as respondents, have violated the provisions of said Acts and the Rules and Regulations promulgated under the Wool Products Labeling Act of 1939 and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent I. Spiewak & Sons, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York as of January 2, 1967. It was previously a New Jersey corporation, organized, existing and doing business under the laws of said State until its dissolution on December 31, 1966.

Respondents Gerald Spiewak, Robert I. Spiewak and Martin H. Spiewak are officers of the corporate respondent. They formulate, direct and control the acts, practices and policies of the said corporate respondent including those hereinafter set forth.

Respondents are manufacturers of wool products with their office and principal place of business located at 10 West 33rd Street, New York, New York.

PAR. 2. Respondents, now and for some time last past, have manufactured for introduction into commerce, introduced into commerce, sold, transported, distributed, delivered for shipment, shipped, and offered for sale, in commerce, as "commerce" is defined in the Wool Products Labeling Act of 1939, wool products as "wool product" is defined therein.