UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA,

Plaintiff,

vs.

PFIZER, INC.,
AMERICAN CYANAMID COMPANY,
BRISTOL-MYERS COMPANY,
OLIN CORPORATION,
SQUIBE CORPORATION,
E.R. SQUIES & SCNS, INC., and
THE UPJOHN COMPANY,

Defendants.

CIVIL ACTION NO. 4-71 CIV. 403

Filed: May 30, 1974

Equitable Relief and Damages Sought

AMENDED AND SUPPLEMENTAL COMPLAINT

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AMENDED AND SUPPLEMENTAL COMPLAINT

The plaintiff, United States of America, by its attorneys, acting under the direction of the Attorney General, brings this civil action in three counts.

COUNT I - CAUSE OF ACTION AGAINST PFIZER, INC., FOR CANCELLATION OF THE TETRACYCLINE PATENT

A. JURISDICTION AND VENUE

1. As a first cause of action, the United States (hereinafter plaintiff), in its sovereign capacity as the grantor of patents issued under the patents laws of the United States, brings this suit against Pfizer, Inc., to obtain a judgment and decree cancelling and annulling U.S. Pat. No. 2,699,054 entitled "Tetracycline" (hereinafter Conover patent)

issued to Pfizer on January 11, 1955, on the ground that it was procured by fraud perpetrated on the Patent Office by Pfizer.

- 2. This first cause of action is filed and the Court has jurisdiction over this action under Section 1338(a) of Title 28 of the U.S. Code which confers on the district courts jurisdiction of civil actions arising under the patent laws of the United States and Section 1345 of Title 28 of the U.S. Code which confers on the district courts original jurisdiction of civil suits commenced by the United States.
- 3. The fraud alleged hereinafter as the basis for this cause of action was perpetrated by Pfizer, Inc., on the U.S. Patent Office. Pfizer, Inc. maintains offices, transacts business and is found within the State of Minnesota. Under the provisions of Section 1391(b) and 1391(c) of Title 28 of the U.S. Code, venue is properly laid in this District.

B. DESCRIPTION OF THE DEFENDANT

- 4. Pfizer, Inc., formerly Chas. Pfizer & Co., Inc. (hereinafter Pfizer) is a corporation incorporated under the laws of the State of Delaware and has its principal office and place of business at 235 East 42nd Street, New York, New York. Pfizer is hereby made a defendant herein.
- 5. Pfizer is the assignee of record of the Conover patent. At the time of filing the Conover application, Conover was an employee of Pfizer and under an obligation to assign all inventions developed in the course of his employment to Pfizer.
- 6. The acts alleged in this complaint to have been done by the defendant were authorized, ordered, or done by its officers, directors, agents, employees or representatives

while actively engaged in the management, direction or control of the affairs of the defendant.

- 7. Other firms referred to in this Amended and Supplemental Complaint are designated by the following abbreviated names:
 - (a) American Cyanamid Company (Cyanamid);
 - (b) Bristol-Myers Company, Bristol Laboratories Division, Bristol Laboratories, Inc. severally and jointly (Bristol);
 - (c) Olin Mathieson Chemical Corporation, Olin Corporation, severally and jointly (Olin);
 - (d) Squibb Corporation, E.R. Squibb & Sons, Inc., severally and jointly (Squibb);
 - (e) The Upjohn Company (Upjohn)

C. BACKGROUND OF PFIZER'S FRAUD ON THE PATENT OFFICE

8. On October 23, 1952 Pfizer filed a patent application (the Conover application) seeking a patent on the product tetracycline, its salts and a process for manufacturing it by the hydrogenation of Aureomycin. On October 9, 1953 Pfizer filed a continuation-in-part of this application and on October 20, 1953 the original application was formally abandoned. On March 16, 1953 Cyanamid filed a patent application (the Boothe-Morton application) seeking a patent on the product tetracycline, its salts and a process for manufacturing it by the hydrogenation of Aureomycin. On September 28, 1953 the Heyden Chemical Corporation applied for a patent (the

Minieri application) on an antibiotic designated HA-20A (which it announced might be tetracycline), its salts, and a process for producing it by direct fermentation. On October 29, 1953 the Patent Examiner rejected the Minieri process claims on the ground that tetracycline was inherently coproduced under the process claimed in Cyanamid's Duggar patent.

- 9. On October 19, 1953 Bristol filed an application for a patent on the product tetracycline (the Heinemann application), its salts and a process for producing it by fermentation. Both the product and process claims of the Heinemann application were rejected by the Patent Office on December 8, 1953 on the assumption that tetracycline was inherently coproduced with Aureomycin under the processes described in Cyanamid's Duggar and Niedercorn patents.
- 10. On November 3, 1953 Cyanamid entered into a contract to acquire the assets of the Antibiotic Division of the Heyden Chemical Corporation including the Minieri tetracycline application.
- 11. At the end of October 1953 Pfizer and Cyanamid became aware that they had pending before the Patent Office competing applications for a patent on tetracycline. Clinical tests had demonstrated the therapeutic efficacy of tetracycline and it was evident that it would be directly competitive with Cyanamid's Aureomycin and Pfizer's Terramycin.

 Both Pfizer and Cyanamid knew that the value of their respective Aureomycin and Terramycin patents and their

dominant positions in the broad spectrum antibiotic market would be impaired by the unrestricted production and sale of tetracycline by other firms. Moreover, they knew that if tetracycline could be sold by other firms in free and open competition, the price of this product as well as that of other broad spectrum antibiotics would be forced downward as the prices of penicillin had been in recent years. Thus, unless entry into the field of producing and selling tetracycline could be prevented by obtaining a patent on tetracycline both Pfizer and Cyanamid stood to have their unusually profitable participation in the broad spectrum antibiotic field undermined and dissipated.

- 12. Anticipating that the Patent Office would declare an interference between their competing applications, the presidents of Pfizer and Cyanamid met in November 1953 and reached the following agreement:
- (a) Pfizer and Cyanamid would exchange proofs with respect to the issue of priority of invention and the loser would file a concession of priority;
- (b) whoever received the patent would license the other under the patent;
- (c) Cyanamid would license Pfizer under its Aureomycin patent to make Aureomycin for conversion by hydrogenation into tetracycline at a royalty of 2-1/2% of net sales of tetracycline; and,
- (d) Cyanamid would sell tetracycline in bulk to

 Pfizer until Pfizer could manufacture its own so as to en
 able Pfizer promptly to commence the marketing of tetracycline.
- (e) Cyanamid would also furnish Pfizer with the cultures of the microorganisms it was using in producing commercial Aureomycin and the technological know-how

relating to the production of Aureomycin. This agreement was formally executed on January 11, 1954.

- 13. The Patent Office declared an interference between Pfizer's Conover and Cyanamid's Boothe-Morton applications on December 28, 1953. After the exchange of proofs relating to the date of discovery, Cyanamid filed with the Patent Office a formal concession of priority to Pfizer and later withdrew its Boothe-Morton application. As a consequence, Pfizer was awarded priority on February 9, 1954 and the interference proceeding between the competing applications was dissolved (i.e., terminated) by the Patent Office.
- 14. On January 15, 1954 Bristol filed a continuation-in-part of its earlier Heinemann application for a patent on tetracycline salts and a fermentation process for making it. On March 2, 1954 the Patent Office declared a second interference, this time on competing claims to tetracycline hydrochloride between Pfizer's continuation-in-part Conover application, Cyanamid's Minieri application and Bristol's continuation-in-part Heinemann application.
- 15. On October 14, 1954 the Patent Examiner on his own motion dissolved the second interference on the ground that tetracycline and tetracycline hydrochloride were not patentable since they did not satisfy the requirement of novelty. The Patent Examiner in his decision stated it appears from the disclosure of the Minieri, et al. appli-

cation that tetracycline was inherently coproduced along with Aureomycin under the processes described in Cyanamid's Duggar and Niedercorn patents. Thereafter, on November 24, 1954 individual formal rejections of the tetracycline product claims in each of the three competing applications were mailed to each of the companies by the Patent Office. The issue before the Patent Examiner as raised by his rejection of all three competing applications was the factual accuracy of his ground of rejection. It is now unquestioned in scientific circles that tetracycline is inherently coproduced along with Aureomycin when using the microorganism and processes of the Duggar and Niedercorn patents and that commercial Aureomycin has always contained some tetracycline.

16. On November 29, 1954 Pfizer's representatives, attorney Werner H. Hutz and Dr. Francis X. Murphy, a patent agent in Pfizer's Legal Division, met with the Patent Examiner concerning his rejection of Pfizer's Conover application and argued that there was no reasonable basis for his conclusion that tetracycline is inherently coproduced in the prior art processes of the Duggar and Niedercorn patents. The Examiner adhered to his position and informed Pfizer that he would not withdraw his rejection unless Pfizer presented proof that no identifiable amounts of tetracycline could be recovered using the microorganisms and processes of the Duggar and Niedercorn patents. At this meeting Pfizer representatives Hutz and Murphy failed to disclose to the Patent Examiner evidence in Pfizer's possession that identifiable tetracycline was

coproduced along with Aureomycin under the Duggar and Niedercorn patents. As a result, it was agreed that Pfizer should conduct certain tests to resolve this issue. After this meeting Hutz and Murphy on November 30, 1954 gave detailed directions to Dr. Fred W. Tanner, Jr. and Dr. Virgil V. Bogert, two Pfizer scientists, as to the specific tests they wanted them to conduct.

17. On December 8, 1954 Hutz and Murphy conferred with the Patent Examiner and filed affidavits by Dr. Tanner and Dr. Bogert describing the tests that they had conducted for the purpose of determining whether any identifiable tetracycline was produced when using the microorganisms and fermentation processes described in the Duggar and Niedercorn patents. The Tanner affidavit dated December 7, 1954 describes the preparation of fermentation broths in accordance with the disclosures in the Duggar and Niedercorn patents. The Bogert affidavit dated December 7, 1954 represented that he had not been able to recover any identifiable tetracycline from the test fermentation broths prepared by Tanner in accordance with the directions in the Duggar and Niedercorn patents. With the affidavits, Pfizer's representatives Hutz and Murphy also filed "Remarks" stating that the affidavits showed that it was not possible to recover any identifiable tetracycline under the prior art of the Duggar and Niedercorn patents and that this demonstrated that the Patent Examiner's contrary assumption was incorrect. The Patent Examiner was not convinced and requested an explanation as to why no further efforts were made to recover identifiable tetracycline from the various amorphous materials showing some degree of antibiotic potency. The amorphous materials had been recovered by various filtering processes from the test fermentation broths which Pfizer represented had been prepared in accordance with the directions in the Duggar patent.

- On December 9, 1954 Hutz and Murphy submitted a supplemental affidavit by Dr. Bogert dated December 8, 1954 responding to the Examiner's request. The supplemental Bogert affidavit stated that the quantity of amorphous material was so small and so low in antibiotic potency that he did not know any method of recovering any clearly identifiable tetracycline from the fermentation broths of the Duggar and Niedercorn processes. After a further meeting with Hutz and Murphy on December 9, 1954 and on the basis of the affidavits of Dr. Tanner and Dr. Bogert submitted by Pfizer representing that the tests conducted showed that no identifiable tetracycline was coproduced along with Aureomycin under the prior art of the Duggar and Niedercorn patents the Patent Examiner withdrew his rejection and issued a Notice of Allowance on Pfizer's Conover application on December 9, 1954. January 11, 1955 U.S. Pat. No. 2,699,054 was issued to Pfizer.
- 19. On January 11, 1955 Pfizer commenced separate infringement suits in the federal district court in Georgia against Bristol, Squibb and Upjohn charging each of them with infringing its tetracycline patent and seeking a restraining order and damages. Bristol, Squibb and Upjohn each filed answers denying the infringement claims. On January 25, 1955 Bristol, Squibb and Upjohn each filed a

declaratory judgment suit in the Southern District of New York against Pfizer asking that the patent be declared invalid and unenforceable. The suits instituted by Pfizer in Georgia were subsequently transferred to the Southern District of New York.

- 20. During 1954 and 1955 Bristol and Upjohn each made several unsuccessful attempts to obtain a license under the tetracycline patent from Pfizer. Bristol was seeking a license to make, use and sell tetracycline and insisted that it had to have at least two bulk customers.
- 21. On September 29, 1954 Cyanamid filed a suit against Bristol alleging that in manufacturing tetracycline Bristol was infringing Cyanamid's Duggar patent on Aureomycin by reason of the fact that Aureomycin was being coproduced.

 On December 11, 1954, two days after the Patent Examiner issued to Pfizer a Notice of Allowance on its tetracycline application, Cyanamid settled its suit against Bristol and agreed to grant Bristol a license to make Aureomycin in connection with its manufacture of tetracycline in return for a royalty of 5% of Bristol's net sales of tetracycline.
- 22. In November of 1955 Bristol entered into separate agreements with Squibb and Upjohn pursuant to which each agreed to purchase its requirements for bulk tetracycline from Bristol for the duration of their tetracycline litigation with Pfizer and for three years thereafter. Each agreed to give Bristol exclusive control over the conduct of its tetracycline litigation with Pfizer including the right to admit the validity of the tetracycline patent. Bristol agreed not to settle with Pfizer on terms that would pre-

clude it from furnishing Squibb and Upjohn with their tetracycline requirements for sale to the drug trade.

- 23. In December of 1955 Bristol and Pfizer entered into negotiations which resulted in the settlement of the tetracycline litigation between Pfizer and Bristol, Squibb and Upjohn, respectively, on the following terms:
 - (a) the three infringement actions by

 Pfizer and the three declaratory judgment
 actions against Pfizer were to be discontinued and terminated by consent;
 - (b) Bristol, on behalf of itself and on behalf of Squibb and Upjohn, admitted the validity of the patent;
 - (c) Pfizer would grant Bristol a license to manufacture, use and sell tetracycline at a royalty rate of 3 1/2% of net sales; and (d). Pfizer would grant licenses to Squibb and Upjohn restricted to the right to purchase, compound, use and sell tetracycline only in finished dosage form and only to the drug trade, at a royalty of 3 1/2% of net sales of tetracycline. The licenses granted by Pfizer to Bristol, Squibb and Upjohn were formally executed on March 28, 1956.
- 24. Except for initial sales by Cyanamid of bulk tetracycline to Pfizer in early 1954 Cyanamid has consistently refused to sell bulk tetracycline to anyone despite numerous requests. Pfizer has consistently refused to sell tetracycline in bulk form until 1966 when it started to sell in bulk form to one customer as part of an agreement settling a tetracycline infringement action it had instituted. Bristol has

consistently refused to sell tetracycline in bulk form to anyone except Squibb and Upjohn. Squibb and Upjohn in compliance with the terms of their licensing agreements with Pfizer have restricted themselves to selling tetracycline only in finished dosage form and only to the drug trade.

- D. PFIZER PERPETRATED A FRAUD ON THE PATENT OFFICE WHICH CAUSED THE TETRACYCLINE PATENT TO ISSUE
- 25. Pfizer was issued U. S. Pat. No. 2,699,054 as a direct result of its fraudulent conduct in prosecuting its Conover tetracycline application before the Patent Office. The nature and details of the fraud perpetrated by Pfizer upon the Patent Office are described in the succeeding paragraphs.
- 26. The principal issue before the Patent Examiner was whether the invention claimed in the Conover patent was novel and therefore patentable, in accordance with the patent laws of the United States.
- 27. In the course of prosecuting its Conover patent application, Pfizer made false and misleading statements to and suppressed and withheld material information from the Patent Office, relevant to the patentability of tetracycline.
- 28. The false and misleading statements made to and the information suppressed and withheld from the Patent Office by Pfizer included the following, among others:
- (a) In the continuation-in-part of its Conover application filed October ⁹, 1953 Pfizer included a sworn affidavit of Lloyd H. Conover dated October 8, 1953, stating that the invention was not known or used before the invention

or discovery claimed in the application and was not in public use or sale in the United States more than one year prior to the date of the application. This affidavit was filed in compliance with the mandatory requirements of Rule 65(a) of the Rules of the Patent Office implementing the provisions of 35 U.S.C. § 102(b) which set forth certain statutory bars to patentability. Before any patent on tetracycline issued, Pfizer officials learned that the above statements in the Conover affidavit were factually incorrect. Nevertheless, Pfizer failed to correct or withdraw the affidavit knowing that the Patent Office would act in reliance upon its statements in passing upon its Conover application which was then pending.

- (b) The failure to disclose that between February and October 1953 Pfizer had subjected a sample of Cyanamid's commercial Aureomycin to tests designed to identify the presence of tetracycline and found it to contain tetracycline.
- (c) The failure to disclose that tetracycline was present in commercial Aureomycin which had been marketed in the United States since 1948 and, consequently, had been in public use or on sale more than one year prior to the filing date of Pfizer's Conover patent application and had been known or used by others in the United States prior to the date of alleged invention of tetracycline as claimed in Pfizer's Conover application.
- (d) The failure to disclose its knowledge that in fermentations using the microorganisms used by Cyanamid in the commercial production of Aureomycin tetracycline was coproduced.

- (e) The failure to disclose that in September and October 1954, as a part of a general research project to develop methods to produce tetracycline by fermentation, a Pfizer scientist, Dr. Fred W. Tanner, Jr., had fermented S. aureofaciens NRRL-2209 in a Niedercorn patent Example 28 medium and found that the antibiotic potency of the resulting broths was less than 10 micrograms per milliliter a potency so low that Dr. Tanner had classified it as so poor in antibiotic potency as containing nothing, no Aureomycin and no tetracycline.
- (f) At the November 29, 1954 conference with the Patent Examiner following the November 24, 1954 rejection of the Conover patent application, Pfizer's representatives, Werner H. Hutz, Pfizer's outside patent counsel, and Dr. Francis X. Murphy, a member of Pfizer's Legal Division and its patent counsel, failed to disclose that:
 - (1) in October 1954 Pfizer scientists, Dr.

 Fred W. Tanner, Jr., and Dr. Virgil V.

 Bogert, prepared a fermentation broth

 pursuant to Example 1 of the Niedercorn

 patent and found fractions thereof to contain

 5 to 10% of tetracycline, and that
 - (2) Dr. Tanner in October 1954, following directions from Dr. Murphy, conducted fermentations using the microorganisms and processes described in the Duggar patent and in each of the 44 examples (including Example 28) in the Niedercorn patent and discarded all

broths except two prepared in accordance with Example 1 of the Niedercorn patent as so low in potency as to be useless for purposes of determining whether tetracycline was coproduced along with Aureomycin.

- (g) At a conference with the Patent Examiner on November 29, 1954 following the November 24, 1954 rejection of the Conover patent application, Pfizer representatives Hutz and Murphy falsely denied the correctness of the Patent Examiner's conclusion that tetracycline was coproduced in the Duggar and Niedercorn fermentation broths as a result of which the Patent Examiner consented to further tests by Pfizer
- (h) In the Remarks filed with the Patent Office by the law firm of Connolly and Hutz on December 8, 1953

 Pfizer falsely stated that:
 - (1) there was "no reasonable basis" for the Patent Examiner's "speculation as to the coproduction of tetracycline in the prior art processes" and falsely stated that "The available evidence is overwhelmingly contrary to the Examiner's assumption;" and,
 - (2) since Cyanamid had failed to discover any tetracycline in its large scale manufacture of Aureomycin this confirmed the fact that tetracycline was not inherently coproduced under the prior art of the Duggar and Niedercorn patents.

- (i) The affidavits of Dr. Tanner and Dr. Bogert submitted to the Patent Office on December 8 and 9, 1954 failed to disclose that following Dr. Murphy's instructions of October 15, 1954 they had conducted fermentations using the strain of <u>S. aureofaciens</u> NRRL-2209 according to Example 1 of the Niedercorn patent and by paper chromatography tests identified tetracycline as being present in quantities of about 5% of the overall antibiotic content.
- (j) The affidavits of Dr. Tanner and Dr. Bogert submitted to the Patent Office on December 8 and 9, 1954 reporting on tests agreed to at the November 29, 1954 conference failed to disclose:
 - (1) the extremely low antibiotic potency of the Duggar test broth (only 6.9 micrograms per milliliter by biological assay and 8.3 by chemical assay);
 - (2) the extremely low antibiotic potency of the Example 28 Niedercorn test broth (only 5.2 micrograms per milliliter by biological assay and 14.3 by chemical assay) and that this potency was only 2% of the antibiotic potency specified in the Niedercorn patent for Example 28; and
 - (3) that the fermentation of Example 28
 of the Niedercorn test broth was conducted
 at a pH factor of 8.1 for the first 6-1/2
 hours a pH factor outside the range specified
 in the patent for obtaining optimum results.

- (k) In the Remarks filed with the Patent Office on December 8, 1954 Pfizer falsely represented:
 - (1) that the two test broths used, one allegedly a duplication of the Duggar patent and the other allegedly a duplication of the Niedercorn patent, were truly "representative" of fermentation broths described in the Duggar and Niedercorn patents, while not disclosing the actual potency figures; and,
 - (2) that the recovery procedures used in the affidavit tests were the "best designed" to show whether appreciable amounts of tetracycline are produced when following the fermentation procedures described in the Duggar and Niedercorn patents whereas, in fact, the recovery procedures used were inappropriate to the recovery of antibiotics from broths of such low potency.
- (1) In the Remarks filed on December 8, 1954 Pfizer representatives falsely stated that the affidavit reporting on the results of the tests showed that it is "not possible to recover any clearly identifiable tetracycline from the prior art broths ..." and that "These results demonstrate that no appreciable amount of tetracycline is formed in the prior art fermentation processes, thereby demonstrating that the Examiner's assumption is incorrect."
- (m) In the Bogert affidavit filed December 8, 1954 the test results are falsely stated to demonstrate that the Duggar and Niedercorn fermentation broths did not contain appreciable amounts of tetracycline.

- (n) The Bogert affidavit filed on December 9, 1954 misleadingly stated in reference to the results of a test to identify tetracycline in the amorphous material recovered from the test broths that "in fact, there was no indication whatever of the presence of tetracycline."
- (o) In the Remarks filed on December 9, 1954 Pfizer representatives falsely stated that "it would be futile to attempt to recover identifiable tetracycline therefrom [the amorphous material recovered from the test broths] by known procedures."
- (p) That between the time Pfizer received its
 Notice of Allowance on December 9, 1954 and the time that the
 patent actually issued on January 11, 1955 Pfizer scientists
 identified tetracycline as being present in the very same
 fermentation broths used in the tests described in the Tanner
 and Bogert affidavits. Pfizer failed to communicate this
 knowledge to the Patent Office despite the fact that it knew
 that the Patent Examiner had withdrawn his November 24, 1954
 rejection of the Conover application and had allowed the patent on
 the basis of the affidavits submitted by Pfizer which reported
 that the tests demonstrated that identifiable tetracycline
 was not coproduced along with Aureomycin using the processes
 of the Duggar and Niedercorn patents.
- 29. During the course of prosecuting its Conover application before the Patent Office, Pfizer was aided and assisted in its effort to have a patent on tetracycline issued by various false and misleading statements and representations made by Cyanamid. Despite its knowledge of the falsity of such

representations and the materiality of such representations to the patentability of tetracycline Pfizer failed to make known to the Patent Office the falsity of such representations and, in fact, cited and relied upon such representations in prosecuting its Conover application.

- 30. In making the aforesaid false and misleading statements and in withholding the aforesaid information Pfizer breached its duty to make a full, fair and accurate disclosure to the Patent Office of material facts bearing on the patentability of tetracycline.
- 31. As a result of the aforesaid misrepresentations and suppression of facts by Pfizer the Patent Examiner was deprived of a complete and truthful statement of the facts necessary for a fair and objective appraisal of the merits of Pfizer's Conover application. Pfizer knew and intended that in passing upon the tetracycline application the Patent Examiner would rely and act upon the representations it made and the information it presented.
- 32. As a direct result of the false and misleading statements and the information suppressed and withheld by Pfizer, the Patent Examiner was induced to withdraw his November 24, 1954 rejection of Pfizer's Conover application and the Patent Office issued to Pfizer a patent on tetracycline. But for such false and misleading statements and withholding of information no patent would have issued to Pfizer because the subject matter of the alleged invention failed to meet the essential requirement of novelty and was unpatentable as a matter of law on each of the following grounds:

- (a) tetracycline was inherently coproduced along with chlortetracycline using the microorganism and processes disclosed in Cyanamid's Duggar patent (U. S. Pat. No. 2,482,055 issued September 13, 1949)and in Cyanamid's Niedercorn patent (U.S. Pat. No. 2,609,329 issued September 2, 1952). Accordingly, tetracycline was anticipated by the prior art and could not be the subject of a valid patent because of the statutory bar set out in 35 U.S.C. § 102(e);
- (b) tetracycline had been in public use or on sale for more than one year prior to the date of the filing of the Conover patent application on October 23, 1952 in that it was present along with chlortetracycline in the antibiotic sold commercially by Cyanamid under the trade name "Aureomycin" since December 1948 and, therefore, could not be the subject of a valid patent because of the statutory bar set out in 35 U.S.C. § 102(b);
- (c) tetracycline was known or used prior to the date of the invention claimed in the Conover application in that it was present along with chlortetracycline in the antibiotic sold commercially by Cyanamid under the trade name "Aureomycin" since December 1948, and, therefore, could not be the subject of a valid patent because of the statutory bar set out in 35 U.S.C. § 102(a).
- 33. Pfizer has continuously asserted and maintained the validity and enforceability of its tetracycline patent and until its expiration, used it to support artificially inflated prices, to exclude actual and potential competition, to place competitors at a cost disadvantage, to maintain and threaten infringement actions, to collect royalties under licenses it issued and in other ways ex-

ploited its tetracycline patent. Pfizer will continue to assert and maintain the validity of its tetracycline patent while retaining the fruits of its fraudulent activity to the prejudice of the plaintiff, the public, the Patent Office, and competitors of Pfizer unless the relief hereinafter prayed for is granted.

PRAYER

WHEREFORE, the plaintiff prays:

- 1. That the court adjudge and decree that Pfizer has procured U.S. Pat. No. 2,699,054 by means of false and misleading statements and the withholding of material information from the Patent Office and that by such conduct Pfizer perpetrated a fraud upon the U.S. Patent Office.
- 2. That Pfizer be ordered to deliver up to the court U.S. Pat. No. 2,699,054 and that said patent be declared cancelled and annulled.
- 3. That Pfizer be enjoined from collecting royalties under U.S. Pat. No. 2,699,054 from any party.
- 4. That Pfizer be enjoined from instituting any legal proceedings and from making any claim or asserting any right or interest under or interposing any defense based on U.S. Pat. No. 2,699,054.
- 5. That Pfizer be ordered to take whatever steps may be necessary to (a) secure the dissolution or vacation of any decree, judgment or injunction which has issued in any legal proceeding to which Pfizer has been a party which enjoins, restrains, or restricts any party from making, using or selling tetracycline; (b) dismiss any presently pending legal proceeding it has instituted

in reliance on the tetracycline pacent; and (c) release any party from any agreement with Pfizer pursuant to which such party is obligated to refrain from making, using, or selling tetracycline; and (d) that Pfizer be ordered to submit to the court within 30 days from the entry of this judgment a report setting forth the actions it has taken to comply with this order.

- 6. That Pfizer be ordered to notify any person with whom it has entered into a licensing agreement under its tetracycline patent or entered into any agreement or settlement of any claim asserted under the tetracycline patent of the cancellation of the patent for fraud.
- 7. That Pfizer be required to send a copy of this Court's judgment cancelling U.S. Pat. No. 2,699,054 to all persons that Pfizer's files and records disclose to have at any time (a) requested a license from Pfizer under U.S. Pat. No. 2,699,054, or (b) engaged in any conduct which Pfizer considered to have constituted an infringement of U.S. Pat. No. 2,699,054.
- 8. That in respect to each and every foreign patent owned by Pfizer (or any company owned, controlled or affiliated with Pfizer) which, in whole or in part, covers any of the subject matter of any of the claims of U.S. Pat. No. 2,699,054 Pfizer be required to transmit by registered mail a certified copy of any final judgment entered in this action cancelling U.S. Pat. No. 2,699,054 to the agency or instrumentality of such government having jurisdiction over matters pertaining to the granting of patents.
- 9. That the plaintiff recover the costs of this suit.
- 10. That the plaintiff have such other and further relief as the court may deem just and proper.

COUNT II. COMMON LAW ACTION OF DECEIT TO RECOVER DAMAGES SUSTAINED AS A RESULT OF FRAUD PERPETRATED ON THE PATENT OFFICE BY PFIZER, CYANAMID AND BRISTOL

A. JURISDICTION AND VENUE

- As a second cause of action, the United States (hereinafter "plaintiff"), in its capacity as a direct purchaser of broad spectrum antibiotics and combination broad spectrum antibiotic products and as a party providing funds for the purchase of such products by public and private agencies under federally assisted programs and pursuant to various foreign aid programs, brings this common law action of deceit against defendants Pfizer Inc., formerly Chas. Pfizer & Co., Inc., ("Pfizer"), American Cyanamid Company ("Cyanamid") and Bristol-Myers Company ("Bristol") to recover damages it has sustained because of the excessive prices it has been required to pay for such products. These damages were sustained as a result of a fraud which each of these defendants perpetrated on the United States Patent Office and which led to the issuance of the Conover patent on tetracycline to Pfizer. But for the fraudulent conduct alleged herein, said patent would not have issued.
- 35. This second cause of action is filed and the Court has jurisdiction under Section 1345 of Title 28 of the U.S. Code, which confers on the District Courts jurisdiction of all civil suits commenced by the United States.
- 36. Pfizer, Cyanamid and Bristol transact business and are found within the State of Minnesota. Under the provisions of Sections 1391(b) and 1391(c) of Title 28 of the U.S. Code, venue is properly laid in this District.

- B. THE CAUSE OF ACTION AGAINST PFIZER,
 CYANAMID AND BRISTOL IS NOT BARRED
 BY THE STATUTE OF LIMITATIONS
- 37. Section 2415(b) of Title 28 of the United States Code provides that every action brought by the United States for money damages "founded upon a tort shall be barred unless the complaint is filed within three years after the right of action accrues." Section 2415(g) provides that any right of action accruing prior to July 18, 1966, the date of the section's enactment, shall be deemed to accrue on July 18, 1966, for purposes of applying the three-year period of limitations. Section 2416(c) provides that for the purpose of computing the time limitation period established in Section 2415(b) for commencing actions brought by the United States there shall be excluded all periods during which "facts material to the right of action are not known and reasonably could not be known by an official of the United States charged with the responsibility to act in the circumstances."
- 38. This cause of action was filed against defendants Pfizer and Cyanamid on July 15, 1969 and hence is within the three-year statute of limitations. As to defendant Bristol, although the conduct alleged as constituting Bristol's fraud on the Patent Office occurred prior to July 18, 1966, facts material to the right of the common law action of deceit against Bristol were not known and reasonably could not have been known to the appropriate officials of the United States Department of Justice who had "the responsibility to act in the circumstances" until some time subsequent to October 5, 1971. Accordingly, this cause of action against Bristol is not barred by the three-year statute of limitations.
- 39. That facts material to the right of action alleged herein against Bristol were not known and reasonably could not have been known to officials of the Department of Justice until some time subsequent to October 5, 1971 is established by the following:
- (a) Bristol concealed and suppressed evidence of its misconduct before the Patent Office in connection with

its prosecution of its tetracycline applications (i) by agreeing in December 1955 to a discontinuance of the Pfizer v. Bristol, Squibb and Upjohn infringement actions and Bristol, Squibb and Upjohn v. Pfizer declaratory judgment actions in return for a license under Pfizer's Conover patent on tetracycline (paras. 19 and 23, supra) thus eliminating the prospect that facts disclosing Bristol's own misconduct would be publicly revealed during the course of those actions, and (ii) by failing to produce certain relevant and material documents reflecting its knowledge of the inherent production of tetracycline under processes disclosed in prior art patents -- a scientific fact which Bristol withheld from the Patent Office and which it denied in various formal representations to the Patent Office -- although such documents were called for and were responsive to formal requests and legal process directed to Bristol in connection with litigation In the Matter of American Cyanamid Company, et al., F.T.C. Docket 7211, filed July 28, 1958 and were directly relevant to material issues in that proceeding.

(b) By letter dated October 5, 1971, counsel for Bristol advised that in response to Plaintiffs' Request for Production of Documents under Rule 34 dated July 8, 1971 and Plaintiffs' Second Combined Set of Interrogatories, Interrogatory No. 50 dated April 30, 1971, it was producing to the plaintiffs certain documents by placing copies in the Document Depository established for such purpose in In Re Coordinated Pretrial Proceedings In Antibiotic Antitrust Actions, 4-71 Civ. 435 (D. Minn.) which includes this action. Among the documents produced were certain documents which are critically relevant to this cause of action against Bristol. It was only after these documents were placed in the depository that the United States, for the first time, obtained them. These Bristol documents (reflecting scientific work in notebooks by Bristol scientists Hunt and Zangari) contain evidence demonstrating that Bristol scientists in December of 1953 and January of 1954 conducted experiments which conclusively established that

Bristol knew, prior to the declaration of the second interference on tetracycline hydrochloride (to which Bristol was a party) and hence prior to the issuance of the Conover patent on tetracycline, that tetracycline was inherently produced under the prior art processes of the Duggar and Niedercorn patents employing the strain of microorganism (NRRL 2209) which Cyanamid placed in a public depository as a condition of the allowance of the Duggar patent on Aureomycin. NRRL 2209 was the only strain of microorganism referred to in the Duggar and Niedercorn patents. not until counsel for the United States obtained copies of the Bristol documents reflecting the scientific work of Hunt and Zangari and had an opportunity to review and analyze them in relation to other evidence that "responsible officials" of the Department of Justice reasonably could have known (1) that Bristol wilfully suppressed and withheld this relevant and material evidence from the Patent Office, and (2) that Bristol had knowingly and wilfully made the false and misleading statements to the Patent Office, as more particularly alleged hereinafter.

40. As a consequence of the foregoing circumstances the running of the three-year statute of limitations applicable to this common law action of deceit against Bristol to recover money damages did not commence until some time subsequent to October 5, 1971. Accordingly this action is not barred by the statute of limitations.

C. DESCRIPTION OF THE DEFENDANTS

- 41. Each of the corporations listed below is named a defendant herein:
- (a) Pfizer Inc., formerly Chas. Pfizer & Co., Inc. ("Pfizer") is a corporation organized and existing under

the laws of the State of Delaware with its principal office and place of business located at 235 East 42nd Street, New York, New York;

- (b) American Cyanamid Company ("Cyanamid") is a corporation organized and existing under the laws of the State of Maine with its general offices located at Wayne, New Jersey;
- Bristol-Myers Company is a corporation (c) organized and existing under the laws of the State of Delaware with its principal office and place of business located at 630 Fifth Avenue, New York, New York. The activities of Bristol-Myers Company in the ethical pharmaceutical field are carried on by its Bristol Laboratories Division. Prior to December 1959 the business and assets of Bristol Laboratories Division were owned and operated as a wholly-owned subsidiary of Bristol-Myers Company under the corporate name Bristol Laboratories, Inc. In December 1959 the bisiness and assets of Bristol Laboratories, Inc., the wholly-owned subsidiary, were transferred to and merged into Bristol-Myers Company. Bristol-· Myers Company and Bristol Laboratories, Inc., are hereinafter severally and jointly referred to as "Bristol" unless otherwise indicated.
- 42. The acts alleged in this complaint to have been done by the corporate defendants were authorized, ordered or done by their officers, directors, agents, employees, or representatives while actively engaged in the management, direction or control of the affairs of the defendants.

D. BACKGROUND OF PFIZER'S FRAUD ON THE PATENT OFFICE

43. Each and every allegation set forth in paragraphs 8 through 24 of Count I of this complaint is here realleged with the same force and effect as if fully set out herein.

E. PFIZER PERPETRATED A FRAUD ON THE PATENT OFFICE WHICH CAUSED THE TETRACYCLINE PATENT TO ISSUE

44. Each and every allegation set forth in paragraphs
25 through 33 of Count I of this complaint is here realleged
with the same force and effect as if fully set out herein.

- F. CYANAMID AIDED AND ASSISTED PFIZER IN OBTAINING THE CONOVER PATENT ON TETRACYCLINE BY PERPETRATING A FRAUD ON THE PATENT OFFICE
- 45. Cyanamid aided and assisted Pfizer in perpetrating upon the Patent Office the fraud alleged hereinabove in the following ways, among others:
- (a) As a part of the Boothe-Morton application of which it was the assignee Cyanamid, on March 16, 1953, filed a sworn affidavit by James H. Boothe and John Morton, II, dated March 13, 1953, stating that the invention claimed was not known or used before the invention or discovery claimed in the application and that it was not in public use or on sale in the United States more than one year prior to the · date of the application. An essential part of the Minieri application filed September 28, 1953, which Cyanamid acquired from the Heyden Chemical Corporation pursuant to the agreement of November 3, 1953, was a sworn affidavit signed by Pasquale Paul Minieri, Herman Sokol and Melvin C. Firman and dated September 27, 1953, which stated that the invention was not known or used before the invention or discovery claimed in the application and was not in public use or on sale in the United States more than one year prior to the date of the application. These affidavits were filed in compliance with the requirements of Rule 65(a) of the Rules of the Patent Office implementing the provisions of 35 U.S.C.

\$102(a) and 102(b) which set forth certain statutory bars to patentability. Before any patent on tetracycline issued Cyanamid officials, including Harvey W. Edelblute, learned that the above statements were factually incorrect. Edelblute was Cyanamid's patent attorney of record in its Boothe-Morton patent application. Nevertheless, Cyanamid failed to withdraw or correct the affidavits despite its knowledge that they were part of the record upon which the Patent Office would rely in passing upon these and other applications for a patent on tetracycline.

- (b) During the course of the prosecution of its Boothe-Morton application on tetracycline the Patent Examiner on November 16, 1953, asked Edelblute whether Cyanamid might have coproduced tetracycline in making Aureomycin. letter dated December 1, 1953, and received in the Patent Office on December 7, 1953, Edelblute responded that "It seems that [Cyamamid] can unequivocally state that there has not been any tetracycline produced by them, inadvertently or otherwise in their [aureomycin] operations " Despite the fact that Cyanamid officials, including Edelblute, learned that Cyanamid's commercial Aureomycin did, in fact, contain tetracycline they failed to withdraw or correct this representation, thereby enabling Pfizer to rely upon it in urging the Patent Examiner to withdraw his November 24, 1954, rejection of Pfizer's Conover application which was based on his speculation that tetracycline was inherently coproduced along with Aureomycin under the prior art of the Duggar and Niedercorn patents.
- (c) In the course of prosecuting its Minieri application after the declaration of the second interference Edelblute, on behalf of Cyanamid, represented to the Patent

Office that tetracycline was not inherently coproduced along with Aureomycin under the prior art of the Duggar and Niedercorn patents:

(1) by filing on June 14, 1954, a Motion to Amend requesting that specified claims relating to a process for producing tetracycline by fermentation be included in the interference and falsely stating:

Insofar as the prior art is concerned, none of Duggar, Sobin, et al., or Nieder-corn 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. . . .

(2) by filing a brief on August 23, 1954, in support of the June 14, 1954, Motion to

Amend which falsely stated:

The present situation differs from the one referred to above [a Patent Office decision in another patent interference] principally in that there is no evidence that tetracycline was inherently produced by the prior art processes of Duggar, Niedercorn, Sobin, or others.

(d) During the course of the second interference Edelblute on behalf of Cyanamid on June 14, 1954, filed a Motion to Dissolve the interference on the ground that tetracycline hydrochloride was not patentably distinct from the product tetracycline as to which it had on February 2, 1954, conceded priority of invention to Pfizer — a motion which if granted meant that Cyanamid would lose all chance of obtaining a product patent on tetracycline hydrochloride. A Motion to Dissolve on the same ground had been made by Pfizer on June 12, 1954.

- (e) By withholding from the Patent Office Cyanamid's knowledge that tetracycline is coproduced in the commercial production of Aureomycin.
- (f) In prosecuting its Niedercorn patent application Cyanamid did not make a public deposit of a culture of the strain of the effective microorganism which Niedercorn actually used in the fermentations described in the application and thereby failed to satisfy the statutory requirement of making a disclosure sufficient to enable others to practice the invention and failed to disclose the best mode of carrying out the invention. When the issue as to whether tetracycline was inherently coproduced along with Aureomycin under the prior art of the Duggar and Niedercorn patents was raised in connection with passing upon competing tetracycline patent applications, Cyanamid failed to disclose to the Patent Office that the microorganism identified as NRRL-2209 and referred to in the Niedercorn application was actually a very much weaker and less effective strain than that actually used by Niedercorn or than that which was used for the commercial production of Aureomycin under the Duggar patent. In fact a more potent strain than NRRL 2209 was employed by Cyanamid in the commercial production of Aureomycin. This higher yielding strain was not deposited by Cyanamid either in connection with the Duggar or the Niedercorn prosecutions although Cyanamid knew of its existence prior to the issuance of either Duggar or Niedercorn, nor was this disclosed to the Patent Examiner at any time before the issuance of the Conover patent despite numerous opportunities to do so, and a duty to do so.
- 46. In making the aforesaid false and misleading statements and in withholding the aforesaid information Cyanamid

breached its duty to make a full, fair and accurate disclosure to the Patent Office of the material facts bearing on the patentability of tetracycline.

- 47. As a result of the aforesaid false and misleading statements and withholding of information by Cyanamid a patent on tetracycline was issued to Pfizer which otherwise never would have been granted.
- 48. While Cyanamid was conducting the prosecution of its Boothe-Morton and Minieri applications before the Patent Office it knew and its counsel Edelblute knew that if Pfizer obtained a patent on tetracycline then pursuant to the Pfizer-Cyanamid agreement of November 1953 (formally executed on January 11, 1954) Pfizer was obligated to give Cyanamid a license to manufacture and sell tetracycline. Cyanamid also knew that Pfizer had made a decision not to license anyone else in the event it obtained a patent and to vigorously enforce any such patent against infringers.
- 49. With knowledge of the contributory role its misconduct played in causing the tetracycline patent to issue Cyanamid continued to participate with Pfizer in exploiting the fraudulently procured tetracycline patent until its expiration on January 11, 1972 by operating under the license it accepted from Pfizer, by paying royalties on the patent and by refraining from contesting its validity despite its knowledge that it was procured by fraud.

G. ADDITIONAL BACKGROUND RELATING TO BRISTOL'S FRAUD ON THE PATENT OFFICE

- 50. In addition to the filing of the Heinemann parent application Ser. No. 388,048 on October 19, 1953, (para. 9, supra) (Heinemann I application) and the continuation-in-part application Ser. No. 404,380 on January 15, 1954 (para. 14, supra) (Heinemann II application) Bristol on January 25, 1954, filed a third Heinemann application Ser. No. 406,062 (Heinemann III application) which was a continuation-in-part application of the two earlier Heinemann I and II applications.
- 51. The Heinemann I application contained claims to the product tetracycline, its salts and a process for producing tetracycline by direct fermentation. The Heinemann II application contained claims to tetracycline salts and fermentation processes for producing the salts. The Heinemann III application contained claims to various forms of tetracycline including forms suitable for therapeutic use, and claims covering processes for the production of such substances by direct fermentation.
- 52. In an Office Action of December 8, 1953 the Patent Examiner rejected the product and process claims of the Heinemann I application on the scientific deduction that tetracycline was inherently coproduced along with Aureomycin under the processes disclosed in Cyanamid's Duggar and Niedercorn patents (para. 9, supra). The Patent Examiner in the same Office Action also rejected the product claims of the Heinemann I application on a Stephens, et al., article published in the Journal of the American Chemical Society, Vol. 74, pp. 4976-4977 (October 5, 1952) by Pfizer scientists on the ground that the article "clearly disclose[s] the concept (name and structure)" of tetracycline.

- 53. In late December 1953 and in early January 1954
 Bristol ascertained from certain experiments its scientist;
 Hunt and Zangari conducted that tetracycline was inherently
 produced along with Aureomycin by the fermentation processes
 disclosed in the prior art of the Duggar and Niedercorn
 patents using the microorganism NRRL 2209, the only microorganism referred to in the Duggar and Niedercorn patents.
 These experiments and the results obtained were described
 in the Hunt and Zangari laboratory notebooks (para. 39,
 supra).
 - 54. In early 1954 Bristol ascertained the presence of tetracycline in seventeen samples of Cyanamid's commercial Aureomycin, fourteen of which had been in public use and on sale more than one year prior to the filing of any of Bristol's, Cyanamid's or Pfizer's patent applications on tetracycline, the only applications on tetracycline pending in the Patent Office. This fact was confirmed by additional scientific tests conducted by Bristol in the fall of 1954.
- 55. Included in the papers filled on January 15, 1954 in support of the Heinemann II application (para. 14, supra) was a Rule 132 affidavit which contained a "verified showing of the superiority of the salts of tetracycline over the free base [tetracycline]." On the basis of this affidavit, Bristol urged in a letter to the Patent Office filled on January 15, 1954, that the claims in the Heinemann II application directed to the salts of tetracycline (including tetracycline hydrochloride) should be considered patentable even if the Stephens et al., article (para. 52, supra) could properly be considered as disclosing the free base tetracycline.
- 56. In an Office Action dated February 8, 1954, in the Heinemann II application the Patent Office advised Bristol that the claim "Tetracycline hydrochloride" was considered patentable and indicated that it would make such a claim

the subject of an interference proceeding. In the same action the Examiner rejected the product claims drawn broadly to salts of tetracycline as being unpatentable over the Stephens, et al., article in view of the Duggar patent and a Sobin patent on the ground that the Rule 132 affidavit filed on January 15, 1954 did not establish that the claimed class of tetracycline salts were patentably distinct from the base tetracycline per se.

- 57. On March 2, 1954, the Patent Office declared Interference No. 86,861 on tetracycline hydrochloride (hereinafter the second interference). Pfizer's Conover continuation-in-part application, Cyanamid's Minieri application and Bristol's Heinemann II application (para. 14, supra), each contained a claim to tetracycline hydrochloride and all three were involved in the second interference.
- 58. During the second interference, Bristol and Cyanamid each made motions asking the Patent Office to add to the interference counts covering various processes for the production of tetracycline and tetracycline hydrochloride, or to institute new interferences on claims to such processes.

 Pfizer and Cyanamid also made motions to dissolve the second interference as to Bristol because of an inadequate disclosure of the microorganism.
- 59. In a decision dated October 14, 1954 the Patent Office dissolved the second interference on the ground that tetracycline and tetracycline hydrochloride were inherently produced under the processes disclosed in the prior art Duggar and Niedercorn patents and hence did not satisfy the novelty requirements necessary for patentability (para. 15, supra). In addition it held that tetracycline hydrochloride was not patentably distinct from tetracycline and that the disclosure of the microorganism in Bristol's Heinemann II application was inadequate to enable others to practice the invention.

- 60. On October 25, 1954 the Examiner rejected the product claims to tetracycline in the Heinemann I application as unpatentable because they did not satisfy the novelty requirements for patentability for the reasons stated in the decision dated October 14, 1954. The Patent Office further rejected the product claims as being unpatentable over the Stephens, et al., article and also as being based upon a fatally defective disclosure due to an inadequate description of the microorganism and a failure to deposit the microorganism employed to produce the claimed product.
- 61. On November 3, 1954 Bristol filed a petition for reconsideration and modification of the October 14, 1954 decision which held that Bristol in its Heinemann II application could not make the claim to tetracycline hydrochloride because of a defective and inadequate disclosure of the microorganism and because tetracycline hydrochloride was not patentably distinct from tetracycline. Bristol did not ask for reconsideration and modification of that portion of the October 14, 1954 decision which dissolved the second interference on the ground of the inherent production of tetracycline. Bristol's petition was denied by the Patent Office on November 19, 1954.
- 62. On November 24, 1954 after each of the competing applications involved in the second interference had been returned to ex parte status, the Patent Office in each of those applications rejected the product claims to tetracycline and tetracycline hydrochloride for the reasons set forth in the decision on October 14, 1954 dissolving the second interference. The Patent Office also rejected all of the product claims in the Heinemann II application on the Stephens, et al., article.

- lengthy affidavit for the signature of one of its scientists
 David L. Johnson. The affidavit described scientific investigations which the affidavit stated "conclusively demonstrates the presence of tetracycline in amounts of two to four per cent" in some 37 samples of commercial Aurecmycin, "most of which were either purchased or obtained or manufactured" more than one year prior to October 23, 1952, the filing date of the parent Conover application, the earliest tetracycline application filed. This affidavit was drafted for use in support of a petition for the institution of a public use proceeding in the Patent Office which Bristol contemplated filing against Pfizer's pending Conover continuation-in-part tetracycline application. Bristol never filed such a petition.
- ex parte rejections of the product claims in each of the Cyanamid, Bristol and Pfizer applications involved in the second interference, Pfizer proceeded with the prosecution of its Conover application. On December 9, 1954, the Patent Office in the ex parte proceeding of the Conover application withdrew its rejection of the product claims and issued a Notice of Allowance. The Conover patent issued on January 11, 1955.
 - 65. It was not until January 3, 1955 that Bristol in the Heinemann I application filed in the Patent Office an affidavit by Herbert W. Taylor, the Bristol scientist having the most direct responsibility for patent matters at Bristol. This affidavit reported work which "conclusively demonstrates" the presence of tetracycline and tetracycline hydrochloride in amounts of two to four per cent in a long list of samples

^{*/} A public use proceeding is a proceeding instituted in the Patent Office to determine whether a claimed invention of a pending patent application has been in public use or on sale during the patental of the craimed invention under 05 0.5.0. 100(b).

of commercial Aureomycin most of which were either purchased, obtained or manufactured more than one year prior to October 23, 1952, the filing date of the parent Conover application. The affidavit, however, did not disclose Bristol's evidence demonstrating the inherent production of tetracycline under the prior art processes of the Duggar and Niedercorn patents. This evidence confirmed the scientific basis for the Patent Office's dissolution of the second interference and the subsequent ex parte rejections in Bristol's, Cyanamid's and Pfizer's applications of the product claims to tetracycline and tetracycline hydrochloride on grounds of the inherent production of tetracycline and tetracycline hydrochloride under the prior art.

- the presence of tetracycline in commercial Aureomycin filed ex parte in the Heinemann I application, which was already under rejection on three other grounds, could not have been cited by the Examiner against Pfizer's Conover application because of the Patent Statute (35 U.S.C. § 181) and Rule 14 of the Patent Office Rules of Practice which require that contents of applications while in exparte prosecution be kept in confidence by the Patent Office.
- 67. On February 25, 1955 about six weeks after the January 11, 1955 issuance date of Pfizer's Conover patent, Bristol filed an Express Abandonment in its Heinemann I application. On May 24, 1955 Bristol filed Express Abandonments in its Heinemann II and III applications. In the Express Abandonments, signed by the inventors Heinemann and Hooper and by Amel R. Menotti, then vice president of Bristol Laboratories, Inc., Bristol stated that it was abandoning the product claims to tetracycline and or tetracycline hydrochloride in the Heinemann I, II and III applications based upon Bristol's view that the claims were unpatentable because of lack of novelty.

- H. BRISTOL AIDED AND ASSISTED PFIZER
 IN OBTAINING THE CONOVER PATENT
 ON TETRACYCLINE BY PERPETRATING
 A FRAUD ON THE PATENT OFFICE
- 68. In prosecuting its Heinemann I, Heinemann II and Heinemann III applications, Bristol knowingly and wilfully perpetrated a fraud on the Patent Office by suppressing and withholding information from, and by making false and misleading statements to, the Patent Office, which Bristol knew were material and relevant to the Patent Office's determination of the patentability of tetracycline, tetracycline hydrochloride and certain process claims for the production of tetracycline and tetracycline hydrochloride. Bristol's misconduct constituted a fraud upon the Patent Office and aided and assisted Pfizer in its fraudulent procurement of a patent on tetracycline as alleged herein.

Bristol's Suppression and Withholding of Material and Relevant Information

- 69. The occasions and circumstances upon which Bristol suppressed and withheld material and relevant information from the Patent Office include the following:
- (a) On February 3, 1954, Bristol filed a response to the Examiner's rejection of December 8, 1953, in the Heinemann I application in which Bristol suppressed and withheld from the Patent Office the evidence its scientists had obtained in December 1953 and January 1954 which established (1) that tetracycline was inherently produced under the processes disclosed in the prior art patents using the deposited microorganism NRRL-2209 referred to in those patents, and (2) that tetracycline was present in commercial Aureomycin in public use and on sale more than one year prior to the filing dates of any of Bristol's, Cyanamid's and Pfizer's tetracycline applications.

- (b) Throughout the pendency of the second interference on tetracycline hydrochloride (para. 57, supra) which extended from March 2, 1954, to November 19, 1954, Bristol continued to withhold from the Patent Office its knowledge of the inherent production of tetracycline under the prior art processes of the Duggar and Niedercorn patents and its knowledge of the presence of tetracycline in samples of commercial Aureomycin manufactured and sold more than one year prior to the filing dates of any of Bristol's, Pfizer's or Cyanamid's tetracycline applications.
- (c) Despite its knowledge that the Exeminer on October 14, 1954, had dissolved the second interference on the express ground of the inherent production of tetracycline under the processes disclosed in the Duggar and Niedercorn patents, Bristol, in its November 3, 1954 petition for reconsideration of the Examiner's decision holding that tetracycline hydrochloride was not patentable to Bristol, continued to withhold from the Patent Office its knowledge of the inherent production of tetracycline under the prior art of the Duggar and Niedercorn patents and its knowledge of the presence of tetracycline in commercial Aureomycin.
- (d) Although Bristol contemplated using its evidence of the presence of tetracycline in Cyanamid's commercial Aureomycin to support a petition requesting the Patent Office to institute a public use proceeding to obtain a determination by the Patent Office that tetracycline and tetracycline hydrochloride were unpatentable under 35 U.S.C. § 102(b) because of prior public use or sale in commercial Aureomycin, Bristol refrained from filing any such petition. As a consequence the Patent Office was again denied the opportunity to consider this evidence in passing upon the patentability of tetracycline.

- 70. The false and misleading statements made by Bristol to the Patent Office during the prosecution of its Heinemann I, II and III tetracycline applications included the following:
- (a) On February 3, 1954 Bristol responded to the Patent Office's December 8, 1953 rejection of the product and process claims of the Heinemann I application.

 Despite Bristol's knowledge based on the work of its scientists Hunt and Zangari in December 1953 and early in January 1954 that the processes of the prior patents inherently produced tetracycline, Bristol, in an effort to convince the Patent Examiner that the basis of his December 8, 1953, rejection was not scientifically correct and thereby induce him to withdraw the rejection, made the following false and misleading representation to the Examiner:

Turning now to the rejection of the product claims 1 to 7 and 18 to 20 as being unpatentable over either of the Duggar and Niedercorn patents, we submit that there is nothing in the references to support the conclusion drawn by the Examiner, namely that Applicants' product must be produced inherently in carrying out the process of the cited patents. . . Accordingly, we submit that the cited art controverts rather than supports the proposition that Applicants' product must be produced inherently in the course of producing Aureomycin. (pp. 41-42 of the Heinemann I file wrapper)

(b) During the pendency of the second interference, Bristol made the following false and misleading statements to the Patent Office concerning the inherent production of tetracycline and the presence of tetracycline in samples of commercial Aureomycin:

(1) On August 20, 1954, in Bristol's "Heinemann, Et Al's Brief In Support Of Their Motions To Amend," which motions were made either to add counts to the second interference or to have further interferences declared between certain of the parties to the second interference, Bristol falsely represented to the Patent Office that a process for producing tetracycline hydrochloride was patentable because the product produced was "a new compound, namely, tetracycline hydrochloride" by stating:

This is directed to a process for producing tetracycline hydrochloride . . . This is obviously a distinctly new process which achieves the novel result of producing a new compound, namely tetracycline hydrochloride. It is obvious that the Stephens, et al. reference has no bearing upon the subject matter of this count. Nor do the Duggar and Sobin et al. patents, of record in the various interfering applications. Those patents are concerned with the production of quite different antibiotic compounds, and they do not disclose the specific steps and conditions recited. It is well recognized that a patentable process is created when certain substances are brought together and caused to react or interact under conditions and in a manner to achieve a new result. (p. 291 of the second interference file wrapper.)

(2) On August 20, 1954, in Bristol's "Brief In Support Of The Party Heinemann Et Al's Motion And Supplemental Motion Under Rule 234 To Include Another Application" Bristol falsely represented to the Patent Office that the product tetracycline produced by the process claimed was a new product and therefore patentable by stating:

The proposed count is thus directed to a novel process for producing a new antibiotic, tetracycline. . . . (p. 324 of the second interference file wrapper.)

* * *

. . . In the case of the proposed count, we have a situation where an admittedly old nutrient medium is subject to the action of an organism capable of producing a new antibiotic to produce this new antibiotic [sic], tetracycline, which is then recovered in the pure state. The result produced by the process is an entirely new one, not anticipated by or suggested by the prior art. Consequently, the process of the count must be a novel one. (p. 326 of the second interference file wrapper.)

(3) On August 20, 1954, in Bristol's "Brief On Behalf Of Heinemann Et Al. In Re Minieri Et Al. Motion To Amend," by adding four proposed counts to processes for producing tetracycline and tetracycline hydrochloride to the interference Bristol again falsely and misleadingly represented to the Patent Office that tetracycline was a new product by stating:

We agree with Minieri et al. that their proposed counts . . . should be considered patentable over the art, since they lead to the production of a new end result [viz. production of tetracycline and tetracycline hydrochloride] . . . (p. 344 of the second interference file wrapper.)

* * *

have a situation in which an admittedly old nutrient medium is subjected to the action of an organism capable of producing a new antibiotic under conditions serving to produce the new antibiotic tetracycline, which is then recovered in the final step. The result produced by the process is an entirely new one, not anticipated by, or suggested by, the prior art. Consequently, the counts should be considered patentable under the established criteria. (p. 345 of the second interference file wrapper.)

71. Bristol made the above representations that tetracycline and tetracycline hydrochloride were new products although Bristol had evidence disclosing that tetracycline and tetracycline hydrochloride were not new products each having been present in Cyanamid's commercial Aureomycin in public use and on sale since 1948 and having been coproduced under the processes disclosed in the prior art of the Duggar and Niedercorn patents.

Bristol's Failure to Correct Statements in Inventors' Oaths After It Learned They Were Factually Incorrect

- 72. As a necessary part of the Heinemann I, II and III applications of which it was the assignee, Bristol in each of the applications filed a sworn affidavit (inventors oath) signed by the named inventors Bernard Heinemann and Irving R. Hooper which asserted that:
 - . . . we verily believe we are the original, first and joint inventors of the invention or discovery . . . described and claimed therein; that we do not know and do not believe that this invention was ever known or used before our invention or discovery thereof, or patented or described in any printed publication in any country before our invention or discovery thereof, or more than one year prior to this application, or in public use or on sale in the United States for more than one year prior to this application; . .

The oaths filed in the Heinemann I, II and III applications were filed in compliance with the requirements of Sections 115 and 116 of the Patent Code (35 U.S.C. §§ 115 and 116) and Rule 65(a) of the Patent Office Rules of Practice implementing the provisions of 35 U.S.C. §§102(a) and 102(b) which set forth certain statutory grounds which bar patentability.

73. Long before any patent on tetracycline or tetracycline hydrochloride issued, Bristol officials in early 1954 obtained scientific evidence that indicated that the factual representations and conclusions in these oaths were factually incorrect. Bristol also knew that an inventors' oath was part of the record upon which the Patent Office relies in determining the patentability of claims in a pending application. Despite this knowledge:

- (a) It was not until January 3, 1955 that Bristol, in the Heinemann I application filed in the Patent Office the Taylor affidavit which reported work which "conclusively" demonstrated the presence of tetracycline and tetracycline hydrochloride in commercial samples of Aureomycin in public use or on sale more than one year prior to the filing dates of any of Bristol's, Cyanamid's or Pfizer's tetracycline applications. This was after Bristol's own prospects for obtaining a patent on tetracycline and tetracycline hydrochloride were virtually eliminated by the Patent Office's October 25, 1954 rejection in the Heinemann I application and the November 24, 1954 rejection in the Heinemann II application on three separate grounds. The affidavit was silent as to Bristol's knowledge that tetracycline was inherently produced under the prior art processes of the Duggar and Niedercorn patents.
- (b) It was not until after the January 11, 1955 issuance of Pfizer's Conover patent on tetracycline and after Bristol had been sued by Pfizer for infringement of the Conover patent that Bristol in the Express Abandonments filed on February 25, 1955 in the Heinemann I application and on May 24, 1955 in the Heinemann II and III applications advised the Patent Office of its view that these facts rendered product claims to tetracycline and tetracycline hydrochloride unpatentable because of lack of novelty.
- 74. That Bristol fully appreciated that the evidence it withheld and concerning which it made false and misleading statements was not only relevant and material but in fact determinative of the non-patentability of tetracycline is reflected by:

- (a) A letter written by John P. Murphy,
 Bristol patent counsel, on April 28, 1955 to foreign patent
 attorneys handling Bristol's foreign tetracycline patent
 applications which stated:
 - . . . Aureomycin, as commercially sold in the United States and elsewhere throughout the world during the entire period when that product has been sold (1949 to date), contained from 2% to 4% of tetracycline. As a result, it is our belief that tetracycline itself lacks novelty and is unpatentable, at least under the laws of the United States. In addition to this lack of novelty because of the public use and sale of Aureomycin, we believe that tetracycline as such, is unpatentable, at least under the laws of the United States, in view of Duggar patent No. 2,482,055 and Niedercorn Patent No. 2,609,329 both of which disclose primarily the use of Streptomyces aureofaciens to produce Aureomycin, since fermentation of this organism in the media disclosed in those patents or, indeed, in any commercial medium, will inevitably produce at least some tetracycline.

Although this letter was written after the tetracycline patent was issued, the facts that form the basis for the expressed belief that tetracycline lacked novelty and was unpatentable were known to Bristol in early 1954.

(b) Express Abandonments were filed by Bristol on February 25, 1955 in the Heinemann I application and May 24, 1955 in the Heinemann II and III applications in which Bristol stated that it was abandoning the product claims to tetracycline and tetracycline hydrochloride based upon its view that they were unpatentable. The abandonments filed May 24, 1955, stated:

^{. . .} Aureomycin, as commercially sold in the United States and elsewhere throughout the world during the entire period when that product has been sold (about 1948 to date) has always contained from 2 to 4% of tetracycline. . . As a result of this lack of novelty, applicants believe tetracycline and tetracycline hydrochloride to be unpatentable.

Applicants' belief that the subject matter discussed above is unpatentable is confirmed by the disclosure of the Minieri application (see Examiner's Motion to Dissolve in Interference No. 86,861 involving the present application) that tetracycline must be produced along with Aureomycin in the fermentation processes disclosed in the prior patents to Duggar, No. 2,482,055, and to Niedercorn No. 2,609,329.

- 75. By withholding information from and by making false and misleading statements to the Patent Office, Bristol breached its duty as an applicant to make a complete, accurate and good faith disclosure to the Patent Office of the relevant and material facts bearing on the patentability of tetracycline. As a result, the Patent Office issued a patent on tetracycline to Pfizer, which otherwise would not have been granted.
- 76. With the knowledge of the contributory role its misconduct played in causing the tetracycline patent to issue, Bristol participated in the benefits of the fraudulently procured patent monopoly by sharing in the commercial exploitation of the patent under the license it received from Pfizer on March 28, 1956 in return for its agreement to terminate the litigation in which Bristol, Squibb and Upjohn were challenging both the validity and enforceability of Pfizer's tetracycline patent.
- 77. Bristol continued to participate with Pfizer in exploiting the fraudulently procured tetracycline patent until its expiration on January 11, 1972, by operating under the license it accepted from Pfizer, by paying royalties on the patent and by agreeing not to contest its validity despite its knowledge that it was procured by fraud.

I. DAMAGES CLAIMED

- 78. The fraudulently procured tetracycline patent has been utilized to foreclose competitors from the tetracycline and broad spectrum antibiotic markets and competition in the manufacture and sale of broad spectrum antibiotic products has thereby been restricted and restrained. All persons except Pfizer and its licensees have been excluded from the tetracycline market. Prices for broad spectrum antibiotics have been maintained at substantially higher levels than would have existed if market entry into the manufacture and sale of tetracycline had not been restricted. As a consequence, the plaintiff has been injured and financially damaged in that:
- (a) it has been required to pay substantially higher prices for purchases of broad spectrum antibiotics and combination broad spectrum antibiotic products than would have been necessary but for the fraudulently procured tetracycline patent and the restrictions on competition which it made possible;
- (b) it has been required to expend and pay out substantially greater sums of money under various domestic programs and foreign aid programs (pursuant to which the plaintiff provides all or part of the funds for the purchase of broad spectrum antibiotics and combination broad spectrum antibiotic products by others) than would have been necessary but for the fraudulently procured tetracycline patent and the restrictions on competition which it made possible. The precise amount of such damages is presently undetermined but is estimated to exceed \$25,000,000.

PRAYER

WHEREFORE, Plaintiff prays:

- 1. That the court adjudge and decree that the defendants Pfizer, Cyanamid and Bristol have perpetrated frauds on the Patent Office which enabled Pfizer to obtain a patent on tetracycline which otherwise would not have been granted.
- 2. That a judgment in favor of the plaintiff be entered against the defendants Pfizer, Cyanamid and Bristol, jointly and severally for the damages suffered by the plaintiff on purchases of broad spectrum antibiotics and combination broad spectrum antibiotic products as a result of the fraudsperpetrated by the defendants on the Patent Office with such interest thereon as is permitted by law.
- 3. That the plaintiff recover the costs of this suit.
- 4. That the plaintiff recover such other amounts and have such other and further relief as the court may deem just and proper.

COUNT III SECTION 4A OF THE CLAYTON ACT TO RECOVER DAMAGES SUSTAINED BY THE UNITED STATES FOR VIOLATIONS OF SECTIONS 1 AND 2 OF THE SHERMAN ACT AND SECTION 7 OF THE CLAYTON ACT

A. JURISDICTION AND VENUE

- 79. As a third cause of action, the United States (hereinafter plaintiff), in its capacity as the direct purchaser of broad spectrum antibiotics and combination broad spectrum antibiotic products and as a party providing funds for the purchase of such products by public and private agencies under Federally assisted programs and pursuant to various foreign aid programs, brings this civil action against the defendants named herein under Section 4A of the Clayton Act (15 U.S.C. § 15A) to recover damages it has sustained as a result of defendants' violations of Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1 and 2) and Section 7 of the Clayton Act (15 U.S.C. § 18).
- 80. Each of the defendants Pfizer, Inc., American Cyanamid Company, Bristol-Myers Company, Olin Corporation, Squibb Corporation, E.R. Squibb & Sons, Inc., and The Upjohn Company transacts business and is found within the State of Minnesota. The interstate trade and commerce described hereinafter is carried out in part in the State of Minnesota and each of the unlawful acts constituting the violations alleged herein have substantially affected said trade and commerce in the District of Minnesota. Under Section 12 of the Clayton Act (15 U.S.C. § 22) and Sections 1391(b) and 1391(c) of Title 23 of the U.S. Code, venue is properly laid in the District of Minnesota.

B. DESCRIPTION OF THE DEFENDANTS

- 81. Each of the corporations listed below is named a defendant herein.
- (a) Pfizer, Inc., formerly Chas. Pfizer & Co., Inc. (Pfizer) is corporation organized and existing under the laws of the State of Delaware with its principal office and place of business located at 235 East 42nd Street, New York, New York.
- (b) American Cyanamid Company (Cyanamid) is a corporation organized and existing under the laws of the State of Maine with its general offices located at Wayne, New Jersey.
- (c) Bristol-Myers Company is a corporation organized and existing under the laws of the State of Delaware with its principal office and place of business located at 630 Fifth Avenue, New York, New York. The activities of Bristol-Myers Company in the ethical pharmaceutical field are carried on by its Bristol Laboratories Division. Prior to December 1959 the business and assets of Bristol Laboratories Division were operated as a wholly-owned subsidiary of Bristol-Myers Company. In December 1959 the business and assets of Bristol Laboratories, Inc., the wholly-owned subsidiary, were transferred to and merged into Bristol-Myers Company. Defendants Bristol-Myers Company and Bristol Laboratories, Inc., are hereinafter severally and jointly referred to as "Bristol".
- (d) Olin Corporation, formerly Olin Mathieson Chemical Corporation, (Olin) is a corporation organized and existing under the laws of the Commonwealth of Virginia with its principal office and place of business located at 120 Long Ridge Road, Stamford, Connecticut. Until approximately 1968 Olin's predecessor, Olin Mathieson Chemical Corporation was, through its subsidiaries, engaged in the manufacture, distribution and sale of ethical pharmaceuticals.

- (e) Squibb Corporation, formerly Squibb, Inc. and Squibb Beech-Nut, Inc., is a corporation organized and existing under the laws of the State of Delaware. It is a holding company wholly owned by Olin Corporation and its principal office and place of business is located at 40 West 57th St., New York, New York 10019. Squibb Corporation operates through four major subsidiaries: E.R. Squibb & Sons, Inc.; Life Savers, Inc.; Dobbs Houses, Inc.; and Lawin-Charles of the Ritz, Inc.
- (f) E.R. Squibb & Sons, Inc. (Squibb) is a corporation organized and existing under the laws of the State of Delaware with its principal office and place of business located at 745 Fifth Avenue, New York, New York. Squibb is a wholly-owned subsidiary of Squibb Corporation and is engaged in the manufacture, distribution and sale of ethical pharmaceuticals. Prior to approximately January 1, 1966 the business and assets of Squibb were operated as the Squibb Division of the defendant Olin. Effective January 1, 1966 Olin transferred all assets and liabilities relating to its pharmaceutical operations to E.R. Squibb & Sons, Inc., a wholly-owned subsidiary. In September 1967 Olin and Beech-Nut Life Savers, Inc. (Beech-Nut) agreed upon a merger of E.R. Squibb & Sons, Inc. and Beech-Nut. In anticipation of the merger Olin transferred all the capital stock of its subsidiary E.R. Squibb & Sons, Inc. in exchange for all of the stock of Squibb, Inc., a corporation newly organized for purposes of effecting the merger. Immediately prior to the merger Olin distributed its entire interest in Squibb, Inc. to Olin's stockholders on a pro-rata basis. On January 15, 1968 Beech-Nut was merged into Squibb Enterprises, Inc., a wholly-owned subsidiary of Squibb, Inc. and the stockholders of Beech-Nut received shares of Squibb, Inc. in

exchange for their stock. The name of Squibb, Inc. was changed to Squibb Beech-Nut, Inc., which on April 30, 1971 changed its name to Squibb Corporation. As a result of these transactions the assets formerly held by E.R. Squibb & Sons, Inc., the Olin subsidiary, are now held by the defendant E.R. Squibb & Sons, Inc. which is a newly organized wholly-owned subsidiary of Squibb Corporation, formerly Squibb Beech-Nut, Inc.

- (g) The Upjohn Company (Upjohn) is a corporation organized and existing under the laws of the State of Michigan with its principal office and place of business located at 301 Henrietta Street, Kalamazoo, Michigan.
- 82. The acts alleged in this complaint to have been done by the defendants were authorized, ordered or done by their officers, directors, agents, employees or representatives while actively engaged in the management, direction, or control of the affairs of the defendants.

C. DEFINITIONS

- 83. As used in this complaint, the term:
- (a) "Antibiotics" means chemical substances produced by microorganisms or by chemical synthesis which have the capacity to inhibit the growth of infections and microorganisms causing disease.
- (b) "Broad spectrum antibiotics" means antibiotics which are effective against a wide range of harmful bacteria including both gram-positive and gram-negative pathogenic bacteria. Such broad spectrum antibiotics include tetracycline, chloratetracycline, oxytetracycline, chloramphenicol, demethly-chlortetracycline, methacycline, doxycycline and minocycline.
- (c) "Combination broad spectrum antibiotics" means ethical pharmaceutical products containing in addition to a broad spectrum antibiotic other therapeutically active ingredients.

- (d) "Chlortetracycline" is the generic name of the broad spectrum antibiotic substance which Cyanamid has marketed under the name "Aureomycin."
- (e) "Oxytetracycline" is the generic name of the broad spectrum antibiotic substance which Pfizer has marketed under the trade name "Terramycin."
- (f) "Chloramphenicol" is the generic name of the broad spectrum antibiotic substance which Parke, Davis & Company has marketed under the trade name "Chloromycetin."
- (g) "Tetracycline" is the generic name of the broad spectrum antibiotic substance which has been marketed by the defendants under various trade names.
- (h) "Tetracycline patent" means U. S. Pat. No. 2,699,054 entitled "Tetracycline" issued to Pfizer as assignee of Lloyd H. Conover on January 11, 1955.
- (i) "Finished dosage form" means pills, tablets, ampules, capsules, solutions, vials, bottles, syrups, and other forms of presenting pharmaceutical products in a manner suitable for use by or administration to the ultimate consumer without further processing or packaging.
- (j) "Drug trade" means retail and wholesale sellers of drugs, hospital, surgical and dental supply houses, retail and wholesale sellers of veterinary drugs, doctors, dentists, veterinarians, hospitals, clinics, and government agencies and government institutions, or any one of them.
- (k) "Bulk form" means the chemical form in which a pharmaceutical product is manufactured but which requires packaging in dosage form so as to render it suitable for sale to the drug trade and dispensing to the ultimate consumer.

D. NATURE OF TRADE AND COMMERCE

- 84. Antibiotics are ethical pharmaceutical products which are dispensed only upon a doctor's prescription. The first antibiotics on the market such as penicillin and streptomycin are normally effective against either grampositive or gram-negative types of bacteria but not both. The later discovered broad spectrum antibiotics, on the other hand, are effective against a wide range of bacteria including gram-positive and gram-negative types. The broad spectrum antibiotics became popularly known as "wonder drugs" because of their rapid action, life-saving qualities and ability to effectively counteract and cure a broad range of illnesses and diseases.
- 85. The first broad spectrum antibiotic sold in the United States was chlortetracycline. Since December 1948 Cyanamid has marketed this product under the trade name "Aureomycin." As the assignee of the Duggar application on September 13, 1949 Cyanamid received U. S. Pat. No. 2,482,055 on "Aureomycin and the preparation of same." On September 2, 1952 Cyanamid, as the assignee of the Niedercorn application, received U. S. Pat. No. 2,609,329 which was an improvement patent on the process for producing Aureomycin.
- 86. On October 4, 1949 Parke, Davis & Co. received U. S. Pat. No. 2,483,885 on the broad spectrum antibiotic chloramphenical and since 1949 it has marketed the product under the trade mame "Chloromycetin."
- 87. On July 18, 1950 Pfizer was granted U. S. Pat. No. 2,516,080 on the broad spectrum antibiotic oxytetracycline

and since 1950 it has marketed the product under the trade name "Terramycin."

- each manufactured by large-scale fermentation of specific microorganisms in vats containing various kinds of growth promoting nutrient media. Tetracycline is manufactured by a process which subjects chlortetracycline to hydrogenation in the presence of a catalyst which substitutes a hydrogen atom for the chlorine atom in the molecule. It is also manufactured by a direct fermentation process. In addition to being manufactured for sale in a variety of dosage forms such as tablets, capsules, suspensions, injectibles, powders, etc., broad spectrum antibiotics are also used in the manufacture of various combination products in which there are other therapeutically active ingredients, such as antihistimines, sulfanilamides, vitamins, and other antibiotics.
 - 89. Cyanamid did not license anyone to manufacture or sell chlortetracycline in the United States, nor did Cyanamid sell chlortetracycline in bulk to anyone. Pfizer did not license any one to manufacture or sell oxytetracycline in the United States, nor did Pfizer sell oxytetracycline in bulk to any one. Parke, Davis & Co. did not license any one to manufacture or sell chloramphenicol in the United States, nor did Parke, Davis sell chloramphenicol in bulk to any one. As a result, each of these three companies enjoyed a monopoly in the production and sale of its respective patented broad spectrum antibiotic in the United States and was the exclusive source of the product in the United States during most of the

life of each of the respective patents. Aureomycin, Chloromycetin and Terramycin each enjoyed a multi-million dollar annual sales volume and were exceedingly profitable products.

- 90. In November of 1953 Cyanamid became the first company to commence the marketing of the new broad spectrum antibiotic, tetracycline, when it introduced this product under the trade name "Achromycin." In view of tetracycline's superior therapeutic qualities Cyanamid decided to concentrate its marketing efforts in the broad spectrum antibiotic field on tetracycline in preference to its Aureomycin. Pfizer commenced marketing tetracycline under the trade name "Tetracyn" in January of 1954. Bristol entered the tetracycline market under the trade name "Polycycline" in April 1954. Squibb commenced selling tetracycline under the trade name "Steclin" in September 1954 and Upjohn followed with its tetracycline under the trade name "Panmycin" in October 1954. Both Squibb and Upjohn purchased tetracycline in bulk form from Bristol and marketed the product in finished dosage form under their respective trade names.
- 91. In introducing its tetracycline patent under the trade name Achromycin in November 1953 Cyanamid adopted the published prices at which it had been selling Aureomycin since October 1951. It also adopted the same dosage forms and package sizes. When Pfizer, Bristol, Squibb and Upjohn introduced their tetracycline products at varying times in 1954 each adopted Cyanamid's published prices as well as the dosage forms and package sizes as used by Cyanamid. These published prices were maintained unchanged until sometime in 1961.

- 92. Tetracycline quickly became the largest selling broad spectrum antibiotic and by 1958 it accounted for approximately two thirds of all sales of broad spectrum antibiotics. At the manufacturer's level sales of tetracycline products in dosage form in 1954 amounted to about \$39,500,000. In 1957 these sales totaled approximately \$114,000,000 and in subsequent years sales have exceeded \$100,000,000 annually.
- 93. With the introduction of tetracycline by Cyanamid in November of 1953, the number of broad spectrum antibiotics in the market increased to four. In 1953 total sales of all broad spectrum antibiotics amounted to \$77,571,581, of which Cyanamid sales represented 44.8% of the market, Pfizer's 47.3% and Pfizer and Cyanamid combined shares being 92.1%. Due to published medical reports of Chloromycetin's adverse side effects, Parke, Davis' sales and market share of the broad spectrum antibiotic market shrunk from \$22,500,000 (22.5%) in 1952 to \$6.1 million (7.9%) of the market in 1953.
- 94. Manufacturer's domestic sales of broad spectrum antibiotic products in dosage form amounted to over \$86,000,000 in 1954. In 1957 these sales amounted to over \$170,000,000 and in 1959 the amount sold was over \$165,000,000. The combined sales of Pfizer, Cyanamid, Bristol, Squibb and Upjohn were approximately 92% of the total broad spectrum antibiotic product market in 1954, 81% in 1957 and 70% in 1959. In 1972 defendants combined sales constituted 88.4% of the total sales of broad spectrum antibiotic products to hospitals and drug stores.
- 95. Sales of broad spectrum antibiotics have constituted a large portion of total dollar sales of Pfizer, Bristol, Squibb and Upjohn and of the Lederle Laboratories Division of Cyanamid.

A large portion of the total profits realized by Pfizer, Bristol, Squibb, Upjohn and the Lederle Laboratories Division of Cyanamid, respectively, have been derived from sales of broad spectrum antibiotics.

- 96. On September 25, 1953, the Heyden Chemical Corporation publicly announced that it had discovered an antibiotic substance which behaved much like tetracycline and which appeared to be similar in all respects to tetracycline and that Heyden had a direct fermentation process for producing it. On September 28, 1953, Heyden applied for a patent (the Minieri application) on the antibiotic substance identified as HA-20A (subsequently amended to read tetracycline) and on a direct fermentation process for producing it. Within only a few days of Heyden's public announcement, Cyanamid entered into negotiations to acquire the Antibiotic Division of Heyden.
- 97. On November 3, 1953 Cyanamid entered into an agreement with Heyden Chemical Corporation to acquire all of the assets of the Antibiotic Division of Heyden and on December 1, 1953 the assets were acquired pursuant to such agreement.

 At the time of its acquisition by Cyanamid on December 1, 1953, the Antibiotic Division of Heyden was engaged in the manufacture and sale of antibiotics, including penicillin, streptomycin, dihydrostreptomycin and neomycin. Heyden sold antibiotics in bulk to other domestic manufacturers, repackagers and to the export trade, but had no marketing organization for selling to wholesalers and retailers.
- 98. In 1952 Heyden had total assets of \$34,769,833, total net sales of all products of \$22,260,714, and total net income

of \$1,205,803. For the first nine months of 1953 Heyden's Antibiotic Division had total net sales of \$2,979,200 of antibiotics and showed a net profit of \$276,700.

- 99. The assets purchased by Cyanamid included the plant and equipment of Heyden's Antibiotic Division and Heyden's patents and patent applications in the antibiotic field including the U. S. Minieri patent application and its foreign counterparts, microorganisms, and work in progress. Many of the leading scientists of the Heyden Antibiotic Division became employees of Cyanamid contemporaneously. The sale price of \$12 million was \$6 million in excess of the book value. For an additional consideration of approximately \$117,000 Cyanamid also purchased Heyden's entire inventory of 84 kilos of tetracycline.
- by Cyanamid it was a highly probable entrant into the tetracycline and broad spectrum antibiotic markets. Heyden had the necessary plant, facilities, scientific technology and know-how, including a productive microorganism and fermentation process for manufacturing tetracycline on a commercial scale. Heyden had a strong incentive to enter the tetracycline market because of the prospect that tetracycline's superior therapeutic qualities indicated that in a short time it would command a substantial share of the large and highly profitable broad spectrum antibiotic market.
- 101. Heyden had commenced pilot plant runs of tetracycline by August of 1953 in preparation for the commercial
 production of tetracycline. By October of 1953 Heyden had
 succeeded in obtaining sufficiently high yields in pilot plant

runs to make commercial production feasible; was conducting in vivo clinical studies of tetracycline in animals and humans; and had consulted the Food and Drug Administration (FDA) concerning the procedures for the certification of tetracycline and the studies and tests necessary to obtain FDA approval for the marketing of tetracycline. An additional indication of Heyden's capability for market entry is the fact that by the date of the acquisition, it had already manufactured 84 kilos of tetracycline. Heyden's technological and production capabilities were such that it could have entered the tetracycline market by selling tetracycline in bulk by the spring of 1954.

- 102. In the first nine months of 1953 Heyden had experienced a net loss of \$422,300 on penicillin sales of \$858,600. As a consequence Heyden had the incentive to convert its unprofitable penicillin production facilities and equipment to the production of tetracycline.
- acquired it had the capability to commence the commercial manufacture of tetracycline and to enter the tetracycline market within a short time. The probability of Heyden's entering the tetracycline market was enhanced by the fact that several pharmaceutical companies with large marketing organizations including The Upjohn Company and Eli Lilly had expressed an interest in purchasing bulk tetracycline from Heyden.
- 104. Up until the fall of 1964, the manufacture of tetracycline for commercial sale in the United States was confined

to Pfizer, Cyanamid and Bristol and the sale of tetracycline was limited to Pfizer, Cyanamid, Bristol, Squibb and Upjohn.

- 105. Pfizer and Cyanamid obtained a large number of United States and foreign patents on various forms and compositions of tetracycline, chlortetracycline and oxytetracycline and their derivatives including patents on demethylchlortetracycline ("Declomycin"), methacycline ("Rondomycin"), doxycycline ("Vibramycin") and minocycline ("Minocin") and processes for producing them.
- 106. Broad spectrum antibiotic products are sold by Pfizer, Cyanamid, Bristol, Upjohn and Squibb to drug wholesalers, retail druggists, private hospitals, tax supported hospitals, veterinarians, clinics, and various Federal, State and local government agencies.
- 107. Each of the defendants have sold and continue to distribute and sell broad spectrum antibiotics including tetracycline to customers located in States other than the State in which it respectively maintains production or processing facilities and in some instances sells to customers located outside the United States.
- 108. On January 11, 1955 Conover U. S. patent No. 2,699,054, on the broad spectrum antibiotic product tetracycline and the process for producing it by the deschlorination of Aureomycin issued to Pfizer. On February 7, 1956, the Minieri patent, U. S. Pat. No. 2,734,018 on a process for the production of tetracycline by direct fermentation issued to Cyanamid.

- 109. Pfizer also obtained foreign counterpart patents of the U. S. Conover patent in many foreign countries.

 In addition to obtaining the U. S. Minieri patent, Cyanamid also obtained counterpart patents in many foreign countries on a direct fermentation process for producing tetracycline. These counterpart patents were filed in reliance on the September 28, 1953 filing date of the U. S. Minieri application.
- 110. Between the time the Conover tetracycline patent issued in 1955 and the end of 1961 Pfizer collected royalties in excess of \$17,146,000 representing a percentage of the net sales price at which licensees Cyanamid, Bristol, Squibb and Upjohn sold tetracycline. Since 1961 and continuing until the expiration of the patent in 1972 Pfizer continued to collect royalties on the Conover patent.

E. OFFENSES CHARGED

111. Beginning in or about November 1953, and continuing thereafter up to and including the date of the filing of this amended and supplemental complaint, the defendants have engaged in an unlawful combination and conspiracy to restrain and to monopolize and have monopolized the above-described trade and commerce in the manufacture and sale of tetracycline and broad spectrum antibiotic products (exclusive of chloramphenicol) in violation of Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1 and 2).

- 112. The substantial terms of the aforesaid combination and conspiracy to restrain and to monopolize the aforesaid trade and commerce in tetracycline and broad spectrum antibiotic products (exclusive of chloramphenicol) have been and are:
- (a) That the patent interference in the United States Patent Office between Cyanamid's Boothe-Morton and Pfizer's Conover applications on tetracycline would be settled by a private exchange of proof on the question of priority and the party determined to have priority would license the other party on any patent it received.
- (b) That Pfizer and Cyanamid prosecute their competing patent applications for tetracycline in such manner that facts disclosing the unpatentability of tetracycline would be withheld from the Patent Office with the result that a patent on tetracycline issued which otherwise would not have issued.
- (c) That Bristol, Squibb and Upjohn join in the pre-existing conspiracy and combination by agreeing to accept licenses under and admitting the validity of the Conover patent on tetracycline despite their knowledge that Pfizer and Cyanamid had made false and misleading statements to and withheld material information from the Patent Office during the prosecution of the Conover application.
- (d) That the manufacture of tetracycline be confined to Pfizer, Cyanamid and Bristol.

- (e) That the sale of tetracycline to the drug trade be confined to Pfizer, Cyanamid, Bristol, Squibb and Upjohn.
- (f) That the defendants refuse to sell tetracycline in bulk form except for bulk sales by Bristol to Squibb and Upjohn.
- (g) That Squibb and Upjohn be restricted to selling tetracycline products only in finished dosage form and only to the drug trade.
- (h) That the several lawsuits between Pfizer and Bristol, Pfizer and Squibb and Pfizer and Upjohn be terminated so as to prevent and avoid a judicial determination:
 - (1) that the tetracycline patent was invalid and/or unenforceable;
 - (2) that Pfizer procured the tetracycline patent by fraud or by inequitable conduct; and
 - (3) that the tetracycline patent had been misused in violation of the Federal antitrust laws.
- (i) That the defendants conceal from the Patent Office, the courts, potential competitors, tetracycline purchasers and the public facts disclosing invalidity and unenforceability of the tetracycline patent.
- 113. During the period of time covered by this amended and supplemental complaint and for the purpose of effectuating and carrying out the aforesaid combination and conspiracy to restrain and to monopolize, the defendants have done the following things, among others:

- (a) Having reason to believe that the Patent
 Office would shortly declare an interference between
 Cyanamid's Boothe-Morton application and Pfizer's Conover
 application, Cyanamid and Pfizer reached agreement in midNovember 1953 on their competing tetracycline patent applications as follows:
 - (1) Pfizer and Cyanamid would exchange proofs with respect to the issue of priority of invention, and the party determined not to have priority of invention would file a concession of priority in the Patent Office.
 - (2) Whoever received the patent would license the other under the patent.
 - (3) Cyanamid would license Pfizer under its Aureomycin patent to make Aureomycin for conversion by hydrogenation into tetracycline at a royalty of 2-1/2% of net sales of tetracycline.
 - (4) Cyanamid would sell tetracycline in bulk to Pfizer until Pfizer could manufacture its own so as to enable Pfizer to promptly commence the marketing of tetracycline, and would also furnish Pfizer with the cultures of the microorganisms it was using in producing commercial Aureomycin and the technological know-how relating to the production of Aureomycin.

- (5) Cyanamid and Pfizer would crosslicense each other royalty-free
 on their respective counterpart
 tetracycline foreign patents, with
 limited sub-licensing rights.
- (b) The agreement described in the foregoing subparagraph (a) was formally executed on January 11, 1954 and
 thereafter each party did what it agreed to do. After
 proofs of priority of invention were exchanged Pfizer and
 Cyanamid agreed that Pfizer was the first inventor and on
 February 2, 1954 Cyanamid filed a concession of priority in
 the Patent Office.
- (c) Pfizer licensed Cyanamid and Bristol to manufacture tetracycline and refused such a license to all other persons until November, 1966.
- (d) Cyanamid accepted a license from Pfizer to manufacture and sell tetracycline and thereafter shared in the exploitation of the patent despite its knowledge that it and Pfizer had made false statements and withheld information from the Patent Office but for which the patent would not have issued.

- (e) Litigation between Pfizer and Bristol, Squibb and Upjohn was suppressed, terminated and settled by the parties in order to prevent and avoid a judicial determination:
 - (1) that the tetracycline patent was invalid and unenforceable;
 - (2) that Pfizer procured the tetracycline patent by fraud; and
 - (3) that the tetracycline patent had been misused in violation of the Federal antitrust laws.
- (f) Bristol, Squibb and Upjohn accepted royalty-bearing licenses under Pfizer's tetracycline patent and agreed not to contest the validity of the patent when, in fact, each of them had information disclosing the invalidity and unenforceability of the patent.
- (g) Pfizer entered into licensing agreements with Squibb and Upjohn which restricted them from manufacturing tetracycline and prohibited them from selling tetracycline in bulk form by expressly limiting them to the sale of tetracycline products only in finished dosage form and only to the drug trade.
- (h) Pfizer refused to sell tetracycline in bulk form.
- (i) Cyanamid sold tetracycline in bulk form to
 Pfizer in early 1954 in order to enable Pfizer to promptly
 commence the marketing of tetracycline but consistently refused
 to sell tetracycline in bulk form to anyone else.
- (j) Bristol sold tetracycline in bulk form to Squibb and Upjohn but consistently refused to sell tetracycline in bulk form to any one else.

- (k) Pfizer has instituted at least 38 infringement suits and has threatened others under its tetracycline patent which it knew to be invalid.
- (1) In infringement suits it instituted, Pfizer used its tetracycline patent to force companies selling tetracycline into agreements which prohibited such companies from engaging in the manufacture and/or sale of tetracycline or products containing tetracycline.
- (m) In May 1954, Pfizer threatened Parke, Davis & Co., with an infringement suit if it purchased tetracycline from Bristol with the result that Parke, Davis & Co. refused Bristol's offer to sell it tetracycline in bulk form.
- (n) During the period 1954 to 1960 defendants refrained from price competition in tetracycline by maintaining identical prices for all tetracycline products marketed by them.
- (o) During the period 1954 to 1960 Pfizer maintained the prices of oxytetracycline, a substitute for tetracycline, at levels identical to defendants' prices for tetracycline products.
- (p) During the period 1954 to 1960 Cyanamid maintained the prices of chlortetracycline, a substitute for tetracycline, at levels identical to defendants' prices for tetracycline products.
- 114. The defendants have monopolized the above-described trade and commerce in the manufacture and sale of tetracycline and broad spectrum antibiotic products (exclusive of chloramphenical) by the following means, methods, and acts, among others:
- (a) Each and every allegation of Paragraphs.8

 through 33 of Count I of this amended and supplemental

 complaint relating to Pfizer's fraud on the Patent Office in

prosecuting and obtaining the Conover patent is here realleged with the same force and effect as if fully set forth herein.

- (b) Each and every allegation of Paragraphs 45 through 49 of Count II of this amended and supplemental complaint relating to Cyanamid's aiding and assisting Pfizer to obtain the Conover patent by making false and misleading statements to and withholding material information from the Patent Office is here realleged with the same force and effect as if fully set forth herein.
- (c) Each and every allegation of Paragraphs 50 through 77 of Count II of this amended and supplemental complaint relating to Bristol's aiding and assisting Pfizer to obtain the Conover patent by withholding material information from and making false and misleading statements to the Patent Office is here realleged with the same force and effect as if fully set forth herein.
- (d) Each and every allegation in Paragraph 113 is here realleged with the same force and effect as if fully set forth herein.
- (e) Cyanamid on November 3, 1953, entered into a contract to acquire all of the assets of the Antibiotic Division of the Heyden Chemical Corporation and acquired such assets on December 1, 1953 pursuant to such agreement, in violation of Section 7 of the Clayton Act (Section 18 of Title 15 of the United States Code).
- (f) The effect of Cyanamid's acquisition of the assets of the Antibiotic Division of Heyden was to substantially lessen competition or to tend to create a monopoly in the above-described trade and commerce in tetracycline and broad spectrum antibiotics (exclusive of chloramphenicol) in the following ways among others:
 - (1) The Patent Office issued a patent on tetracycline that it otherwise would not have issued as a result of Cyanamid's use of its control over the prosecution

- of the Minieri application to suppress and withhold information from and to make false and misleading statements to the Patent Office.
- (2) Heyden was eliminated as a potential market entrant and competitor in the tetracycline and broad spectrum antibiotic markets.
- (3) Heyden was eliminated as a potential supplier of tetracycline in bulk form to companies for repackaging in dosage forms for resale in the wholesale and retail markets, and the hospital, Government and veterinary markets.
- (4) Potential competitors of Cyanamid and the other defendants who would have purchased tetracycline in bulk form from Heyden were foreclosed from entering the tetracycline and broad spectrum antibiotic markets.
- (5) The then existing stable and non-competitive price structures of the tetracycline and broad spectrum antibiotic markets were maintained and perpetuated due to the elimination of Heyden as a potential competitor and as a supplier of bulk tetracycline.

- (6) Cyanamid's and Pfizer's dominant position in the manufacture and sale of tetracycline and broad spectrum antibiotics was further entrenched and strengthened to the detriment of competition.
- (7) Cyanamid's acquisition of Heyden's scientific and technological know-how, eliminated this source of assistance to other potential market entrants.
- (8) Cyanamid obtained a U.S. patent on the Minieri application covering the process of producing tetracycline by direct fermentation and also obtained counterpart patents in many foreign countries.
- (9) Heyden was eliminated as a company that would have had the incentive and ability to challenge the validity and/or the enforceability of any patent on tetracycline that issued.
- (10) Cyanamid and Pfizer were aided in dominating and controlling the production and sale of tetracycline in the United States domestic market and in the United States import and export markets by the ability to use the exclusionary power of the U. S. Minieri patent and

its foreign counterpart patents and the U. S. Conover patent and its foreign counterpart patents to foreclose competition.

- (g) More than a year before Bristol joined with the other defendants in the illegal monopolization,

 Cyanamid, in an effort to exclude Bristol from the tetracycline market, filed suit against Eristol on September 29, 1954 alleging that Bristol's tetracycline manufacturing operations infringed the Cyanamid's Duggar patent on Aureomycin.
- (h) In settling the infringement action which Cyanamid brought against Bristol charging infringment of the Duggar patent, Bristol on January 13, 1955 accepted a license under and admitted validity and infringement of the Duggar patent despite Bristol's belief that it was not infringing and that Cyanamid was misusing the Duggar patent in an effort to prevent competition in tetracycline which was then an unpatented product.
- (i) The defendants, having deterred others from competing in research and development of new and improved technology by reason of the exclusionary power of the dominating tetracycline, Aureomycin and Terramycin patents, maintained and extended their monopoly position in the tetracycline and broad spectrum antibiotic fields by acquiring additional patents on derivatives of tetracycline, chlortetracycline and oxytetracycline.
- (j) Pfizer refused to license anyone in the United States under its Terramycin patent.
- (k) Pfizer refused to sell Terramycin in bulk form to anyone in the United States
- (1) Cyanamid refused to license anyone in the United States under its Aureomycin patent except for

limited licenses to Pfizer and Bristol permitting them to manufacture limited amounts of Aureomycin in the process of manufacturing tetracycline.

- (m) Cyanamid refused to scll Aureomycin in bulk form in the United States.
- (n) Bristol entered into agreements with Upjohn and Squibb, respectively, which required Upjohn and Squibb to purchase all their requirements for tetracycline in bulk form from Bristol.
- (o) Pfizer utilized the services of the U.S.

 Bureau of Customs to conduct a customs watch to detect the date,
 place and consignee of tetracycline imported into the United
 States.
- (p) Pfizer and Cyanamid filed administrative claims against the United States for compensation for Government purchases of tetracycline and Aureomycin from unlicensed suppliers in an effort to deter the United States Government from purchasing tetracycline from foreign sources.

- (q) In July 1964, McKesson & Robbins, Inc. (McKesson), the nation's largest pharmaceutical wholesaler, completed arrangements to purchase on a continuing basis large quantities of tetracycline in bulk from Rachelle Laboratories, Inc. for sale to the drug trade under the name 'McKesson Tetracycline." On or about July 31, 1964, McKesson publicly announced these arrangements, as well as the fact that it would sell its tetracycline to the trade at one-third of the price then charged by the defendants. Cyanamid, one of McKesson's major suppliers of pharmaceutical products, immediately cancelled its wholesaler agreements with McKesson, refused to deal with McKesson as a wholesaler of any of its pharmaceutical products and publicized said actions on its part to the drug trade generally. Simultaneously, Pfizer publicly announced that it would file suit against McKesson for infringement of its tetracycline product patent, which suit was filed approximately one week later.
- (r) In November 1966, in order to secure the dismissal of claims that it had combined and conspired with the other defendants in violation of the antitrust laws and that its tetracycline product patent was invalid and had been procured and misused in violation of the antitrust laws, Pfizer settled the patent infringement action which it had instituted against International Rectifier Corporation and Rachelle Laboratories, Inc. in October, 1962, and granted them a royalty-bearing domestic license under said invalid patent.

- (s) On November 23, 1966 Pfizer, in order to secure the dismissal of claims that it had combined and conspired with the other defendants in violation of the antitrust laws and that its tetracycline product patent was invalid and had been procured and misused in violation of the Federal antitrust laws, settled the patent infringement action which it had instituted against Premo Pharmaceutical Labs, Inc. (Premo), in September, 1963. As a part of the settlement agreement, Premo was required to purchase from Pfizer all of its requirements for bulk tetracycline until December 31, 1967 and one half of its requirements for each subsequent calender year until December 31, 1971.
- the dismissal of claims that Pfizer and Cyanamid had combined and conspired in violation of the antitrust laws and that Pfizer's tetracycline product patent was invalid and had been procured and misused in violation of the antitrust laws, agreed with McKesson to settle the suits then pending between McKesson and Pfizer and Cyanamid. Pursuant to this agreement in early 1967 the actions between McKesson and Pfizer and Cyanamid were thereafter dismissed and Pfizer granted McKesson a license to sell tetracycline under Pfizer's invalid tetracycline product patent on the condition and in exchange for McKesson's agreement to purchase from Pfizer one-half of its tetracycline requirements during each calendar year from 1967 through 1971 inclusive.

F. EFFECTS

115. The effects of the foregoing violations have been and continue to be that:

- (a) The Patent Office was induced to issue a patent on tetracycline which would not have issued but for the false and misleading statements of, and information suppressed and withheld by Pfizer, Cyanamid and Bristol.
- (b) The defendants have exploited an unlawfully obtained monopoly position in the manufacture and sale of tetracycline and have realized monopoly profits on their sale of tetracycline products and other broad spectrum antibiotics (exclusive of chloramphenical).
- (c) The manufacture of tetracycline has been confined to Pfizer, Cyanamid and Bristol and potential competitors of the defendants have been excluded from the manufacture and sale of tetracycline.
- (d) The defendant Bristol has been restricted to selling tetracycline in bulk form only to Squibb and Upjohn.
- (e) All persons except Squibb and Upjohn were foreclosed a source of supply for tetracycline in bulk form.
- (f) Squibb and Upjohn have been excluded from the manufacture of tetracycline.
- (g) Squibb and Upjohn have been restricted to selling the tetracycline only in finished dosage form and only to the drug trade.
- (h) Litigation between Pfizer and Bristol,
 Squibb and Upjohn has been terminated and suppressed
 thereby preventing and avoiding a judicial determination:
 - (1) that the tetracycline patent was invalid and unenforceable;
 - (2) that Pfizer procured the tetracycline patent by fraud or by inequitable conduct, and

- (3) that Pfizer has misused the tetracycline patent in violation of the Federal antitrust laws.
- (i) The unusually high price levels which Cyanamid maintained on its Aureomycin products and which Pfizer maintained on its Terramycin products have been protected and insulated from the competition that would have resulted but for the issuance of a patent on tetracycline.
- (j) The defendants have maintained high, arbitrary and unreasonable prices for the broad spectrum antibiotics sold by them in the United States.
- (k) Competition by others in research and in the development of new and improved technology in the tetracy-cline and broad spectrum antibiotic fields was deterred.
- (1) The defendants obtained a near monopoly of research and technology in the tetracycline and broad spectrum antibiotic fields, much of which was covered by commercially important patents obtained on derivatives of tetracycline, chlortetracycline and oxytetracycline and processes for their production.

G. DAMAGES CLAIMED

- 116. As a result of the aforesaid antitrust violations by the defendants the plaintiff has been injured and financially damaged in that:
- (a) it has been required to pay substantially higher prices for purchases of broad spectrum antibiotics and combination broad spectrum antibiotic products than would have been necessary in the absence of the antitrust violations alleged;
- (b) it has been required to expend and pay out substantially greater sums of money under various domestic

programs and foreign aid programs (pursuant to which the plaintiff provides all or part of the funds for the purchase of broad spectrum antibiotics and combination broad spectrum antibiotic products by others) than would have been necessary but for the antitrust violations alleged herein. The precise amount of such damages is presently undetermined.

PRAYER

WHEREFORE, the plaintiff prays:

- 1. That the Court adjudge and decree that the defendants
 (a) have engaged in a combination and conspiracy to restrain
 and to monopolize the aforesaid trade and commerce in tetracycline and broad spectrum antibiotic products (exclusive of
 chloramphenicol) in violation of Sections 1 and 2 of the
 Sherman Act; and (b) have monopolized the aforesaid trade
 and commerce in tetracycline and broad spectrum antibiotic
 products (exclusive of chloramphenicol) in violation of Section
 2 of the Sherman Act and (c) that Cyanamid violated Section 7
 of the Clayton Act by its acquisition of the assets of the
 Antibiotics Division of the Heyden Chemical Corporation.
- 2. That a judgment in favor of the plaintiff be entered against the defendants jointly and severally for the damages suffered by the plaintiff on purchases of broad spectrum antibiotics and combination broad spectrum antibiotic products as a result of the defendants' violations of the antitrust laws as provided for in Section 4A of the Clayton Act (15 U.S.C. \$ 15A), together with such interest thereon as is permitted by law.
 - 3. That the plaintiff recover the costs of this suit.

4. That the plaintiff recover such other amounts and have such other and further relief as the Court may deem just and proper.

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DATED: