

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,
Department of Justice,
Washington, D.C. 20530;

Plaintiff

v.

Civil No. 822-70

BRISTOL-MYERS COMPANY,
1155 15th Street, N.W.,
Washington, D.C. 20005;

BEECHAM GROUP LIMITED,
Beecham House,
Great West Road,
Brentford, Middlesex,
England; and

Filed: March 19, 1970

BEECHAM INC.,
65 Industrial South,
Clifton, New Jersey 07012;

JURY TRIAL DEMAND

Defendants.

COMPLAINT FOR DECLARATORY AND
INJUNCTIVE RELIEF AND FOR DAMAGES

The United States of America, plaintiff, brings this civil action under Section 4 of the Sherman Act (15 U.S.C. § 4), in order to prevent and restrain the defendants from violating Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1 and 2), and to secure ancillary declaratory relief; and under Section 4A of the Clayton Act (15 U.S.C. § 15a), in order to recover damages suffered by plaintiff as a result of said violations; and alleges:

I. THE DEFENDANTS

1. The defendant Bristol-Myers Company (hereafter referred to as "Bristol") is a Delaware corporation, with its principal office at 630 Fifth Avenue, New York, New York 10020. Bristol is

extensively engaged in the manufacture and sale of pharmaceutical and other products. In 1968 Bristol had total sales of approximately \$83 million and total assets of approximately \$52 million.

2. The defendant Beecham Group Limited is a corporation of Great Britain, with its principal office at Beecham House, Great West Road, Brentford, Middlesex, England. It is extensively engaged in the manufacture and sale, among other things, of semisynthetic penicillins (hereafter defined). For the fiscal year ended March 31, 1969, it had total sales of approximately \$320 million; its total assets as of such date were approximately \$320 million.

3. The defendant Beecham Inc., a New Jersey corporation, is a 90% owned subsidiary of Beecham Group Limited, with its principal office located at 65 Industrial South, Clifton, New Jersey 07012. Beecham Inc. was incorporated in 1967, as the corporate successor to Beecham Products Inc. (then a wholly owned New Jersey subsidiary of Beecham Group Limited). Beecham Inc. is extensively engaged in the manufacture of semisynthetic penicillins (hereafter defined). It operates a \$5 million facility at Piscataway, New Jersey, for this purpose and is presently doubling its manufacturing capacity. For the fiscal year ended March 31, 1959, Beecham Inc. had total sales of approximately \$77 million; its total assets as of such date were approximately \$46 million.

4. Prior to April 1, 1964, Beecham Research Laboratories Limited was a corporation of Great Britain wholly owned by Beecham Group Limited and primarily engaged in research and development of new products. On

April 1, 1964, the principal assets of Beecham Research Laboratories Limited were transferred to Beecham Group Limited and its major business operations were assumed by the Beecham Research Laboratories Branch of the Pharmaceutical Division of Beecham Group Limited. Beecham Group Limited, Beecham Research Laboratories Limited, Beecham Products Inc., and Beecham Inc. are hereafter referred to, whether individually or collectively, as "Beecham," unless it is otherwise specifically indicated.

II. JURISDICTION AND VENUE

5. Bristol transacts business and is found within the District of Columbia.

6. Beecham Group Limited does not reside in the United States. It is the owner of U.S. Patent No. 2,985,648, which is involved in this proceeding. Beecham has not designated in the Patent Office any person residing in the United States on whom may be served process or notice of proceedings affecting such patent or rights thereunder. This is a proceeding affecting such patent and rights thereunder. Pursuant to 35 U.S.C. § 293, this Court has jurisdiction to take any action respecting such patent and rights thereunder, in the same manner as if Beecham were personally within the jurisdiction of the Court.

III. DEFINITIONS

7. As used in this Complaint:

(a) "Natural penicillin" means any penicillin which is produced entirely by fermentation processes (with or without precursors);

(b) "Semisynthetic penicillin" means any penicillin which is produced other than entirely by fermentation processes (with or without precursors);

(c) "Ampicillin" is the generic name for and means the semisynthetic penicillin known by the chemical name "D-(—)-alpha-aminobenzylpenicillin";

(d) "Ampicillin trihydrate" means the form of ampicillin in which each ampicillin molecule is chemically bound to three molecules of water;

(e) "The ampicillin patent" means U.S. Patent No. 2,985,648, with an effective filing date of October 6, 1958, issued to Beecham, May 23, 1961 -- claiming ampicillin as a composition of matter;

(f) "The ampicillin trihydrate patent" means U.S. Patent No. 3,157,640, with filing date of March 21, 1963, issued to Bristol, November 17, 1964 claiming ampicillin trihydrate as a composition of matter;

(g) "Dosage form" means pills, tablets, capsules, vials, ampules, and other forms of packaging pharmaceutical products for use by or administration to the ultimate human or animal consumer thereof; "dosage form" is synonymous with "consumer package form," "pharmaceutical package form," and "pharmaceutical speciality form";

(h) "Bulk form" means the form in which pharmaceutical products are manufactured, prior to the packaging thereof into dosage form.

IV. NATURE OF TRADE AND COMMERCE

3. Semisynthetic penicillins are antibiotic agents used in the treatment of bacterial diseases. The

semisynthetic penicillin ampicillin possesses distinctive biological and chemical properties which, in certain circumstances, makes it a more effective and safe antibacterial agent than natural penicillins or other antibiotics such as tetracycline. The usefulness of commercially significant natural penicillins, for example, is limited to the treatment of diseases caused by so-called "gram-positive" bacteria. Ampicillin, however, is useful against both gram-positive and so-called "gram-negative" bacteria, giving rise to its characterization as a "wide-spectrum" antibacterial agent. Although other wide-spectrum antibacterial agents (e.g., tetracycline and chloramphenicol) are in use, ampicillin is, in many circumstances, prescribed in preference to them because it generally is considerably less toxic and less productive of side-effects and because it is bactericidal (i.e., kills bacteria) instead of merely bacteriostatic (i.e., inhibits the growth of bacteria).

9. In 1968 Bristol, Beecham and their licensees had world-wide sales of semisynthetic penicillins amounting to approximately \$170 million. In 1968 Bristol, Beecham, and their licensees had total sales in the United States of semisynthetic penicillins amounting to approximately \$85 million, almost all of which was in various forms of ampicillin. Such sales of ampicillin in the United States by company and tradename were approximately as follows:

<u>Company</u>	<u>Trade Name</u>	<u>1968 Sales</u>
Bristol	Polycillin	\$52.2 million
AMHO (Ayerst Division)	Penbritin	14.0 million
AMHO (Wyeth Division)	Omnipen	10.0 million
Parke, Davis	Amcill	3.4 million
Squibb	Principen	3.3 million

Bristol, Beecham, and its licensees had total sales in the United States of approximately \$1.5 million for dicloxacillin and oxacillin, two other semisynthetic penicillins. There are at least six other known semisynthetic penicillins, presently of lesser commercial significance: clocxacillin, methicillin, phenethicillin, propicillin, nafcillin, and hetacillin. The United States Government purchases approximately \$6 million of ampicillin and other semisynthetic penicillins annually and it subsidizes the purchase of substantial additional quantities through various aid and grant programs.

10. A substantial portion of the foregoing sales of ampicillin and other semisynthetic penicillin products were made to persons located in states other than the states or countries in which such products were manufactured.

V. BACKGROUND

11. On February 2, 1961, Beecham filed its application for the ampicillin patent. The ampicillin patent issued to Beecham on May 23, 1961, after Beecham and Bristol procured it by committing various fraudulent acts and inequitable impositions upon the Patent Office, as alleged below in greater detail in paragraph 16.

12. On March 21, 1963, Bristol filed its application for the ampicillin trihydrate patent. By that date, however, (a) the manufacture of ampicillin trihydrate had been disclosed more than one year prior thereto, in the ampicillin patent; and (b) the state of the penicillin art was such that it was obvious to produce ampicillin in the trihydrate form.

13. The defendants own or have the right to license various other patents and unpatented technology related to semisynthetic penicillins.

VI. VIOLATIONS CHARGED

14. Beginning at least as early as 1959, and continuing thereafter up to and including the date of filing of this Complaint, the defendants have, in violation of §§ 1 and 2 of the Sherman Act, engaged in a combination and conspiracy in unreasonable restraint of the aforesaid trade and commerce in ampicillin and other semisynthetic penicillins; have entered into and maintained in effect contracts in unreasonable restraint of such trade and commerce; have combined and conspired to monopolize such trade and commerce; and have monopolized the aforesaid trade and commerce in ampicillin.

15. Said violations have consisted of a continuing agreement, understanding, concert of action, and course of dealing among defendants to lessen competition in, exclude competitors from, and control entry into the manufacture and sale of ampicillin and other semisynthetic penicillins, and to secure power over the price of said products, by doing, among other things, the following:

(a) Fraudulently procuring and enforcing the ampicillin patent;

(b) Restraining and preventing the sale of semisynthetic penicillins in bulk form; and

(c) Restraining and preventing the sale of semisynthetic penicillins under other than specified trade names.

In furtherance and pursuance of the aforesaid violations, the defendants did, among other things the acts alleged below in paragraphs 16 through 20.

16. During the pendency before the Patent Office of Beecham's application for the ampicillin patent, defendants, in order to procure said patent, committed fraudulent and inequitable impositions upon the Office, by doing, among other things, the following:

(a) Failing to bring a reference to the attention of the patent examiner, despite defendants' knowledge and belief that such reference constituted a closer reference to the claimed invention than the prior art being considered by the examiner;

(b) Delaying the publication of an article that explained the significance of such reference, until after the issuance of the ampicillin patent by the Office; and

(c) Reporting in a deceptive and misleading manner the results of experiments conducted upon request of the examiner, by filing with the Office false, deceptive, and misleading affidavits relating to such experiments.

17. After the ampicillin patent issued, defendants, knowing full well that said patent had been fraudulently procured and was invalid, used said patent to restrain, prevent, and suppress competition in the sale and distribution of ampicillin by, among other things:

(a) Collecting substantial sums of money as royalties under license and sublicense agreements based upon such spurious patent; and

(b) Instituting a patent infringement suit under said fraudulently procured and known invalid patent.

18. Beecham and Bristol entered into an agreement dated April 2, 1959. Pursuant to such agreement Beecham licensed Bristol, with the right to sublicense, under all of Beecham's existing United States semi-synthetic penicillin patents and future such patents for which applications were filed within the next two years; and agreed to disclose related know-how to Bristol during such period. Beecham and Bristol further agreed that in the United States Beecham would be limited to selling semisynthetic penicillins solely in dosage form under its own trademarks, and that Beecham would not license other persons to sell semi-synthetic penicillins in any form in the United States. Bristol agreed to assign to Beecham all of Bristol's present and future United States and foreign semi-synthetic penicillin patents and know-how for two years following the date of execution of the agreement.

19. Beecham and Bristol entered into several agreements dated January 1, 1967, pursuant to which, among other things:

(a) Bristol licensed Beecham under the ampicillin trihydrate patent, to sell such product only in dosage form under Beecham trademarks; and

(b) Beecham and Bristol cross-licensed one another to practice semisynthetic penicillin patents granted since 1961 in the United States and Canada, with the mutual restriction that each would sell the licensed products only in dosage form under its own trademarks.

20. Defendants have entered into agreements with other drug companies pertaining to the licensing of patents and technology relating to ampicillin and other semisynthetic penicillins, containing, among other restrictive provisions prohibitions against sales in bulk form or under other than a specified trademark.

VII. EFFECTS

21. The effects of the aforesaid violations have been, are, and will be, among others:

(a) To secure to the defendants the power to exclude competitors from the manufacture and sale of ampicillin, and to confer upon the defendants power over the price of ampicillin;

(b) To maintain high, arbitrary, and non-competitive prices for ampicillin;

(c) To secure to the defendants the dominant share of sales in the United States of ampicillin;

(d) To prevent, restrain, lessen, and eliminate actual and potential competition in the manufacture and sale of ampicillin and other semisynthetic penicillins, among defendants and between them and third parties;

(e) To prevent defendants from competing with one another and third persons in the sale in bulk form of ampicillin and other semisynthetic penicillins; and to prevent third persons from obtaining ampicillin and other semisynthetic penicillins in bulk form and thereafter packaging and reselling such goods to consumers;

(f) To prevent defendants and their licensees from selling ampicillin and other semisynthetic penicillins, without labels, generically, or under independent labels or trade names;

(g) To prevent third persons from obtaining ampicillin and other semisynthetic penicillins, packaged for them without labels, generically, or under independent labels or trade names, and thereafter reselling such goods to consumers; and

(h) To deprive the public, and in particular consumers of drugs, of the benefits of free and open competition in the manufacture and sale of ampicillin and other semisynthetic penicillins.

VIII. DAMAGES CLAIMED

22. As a result of the aforesaid Sherman Act violations by the defendants, the plaintiff has been injured and financially damaged in that:

(a) It has paid and is paying substantially higher prices for its purchases of ampicillin than it would have paid, but for such violations;

(b) It has expended and is expending substantially greater sums of money under various domestic and foreign aid programs (pursuant to which the plaintiff provides all or part of the funds for the purchase of ampicillin) than it would have expended, but for such violations.

The exact amount of such damages is presently undetermined.

PRAYER

WHEREFORE, the plaintiff prays:

1. That the Court adjudge and decree that defendants have violated Sections 1 and 2 of the Sherman Act, by engaging in a combination and conspiracy in unreasonable restraint of trade and commerce in ampicillin and other semisynthetic penicillins; by entering into and maintaining in effect contracts in unreasonable restraint of such trade and commerce; by combining and conspiring to monopolize such trade and commerce; and by monopolizing trade and commerce in ampicillin.

2. That the Court adjudge and decree that defendants have fraudulently procured and fraudulently enforced the ampicillin patent, and that it cancel such patent.

3. That the Court declare invalid the ampicillin patent and the ampicillin trihydrate patent, and permanently enjoin defendants from purporting to assert any rights thereunder.

4. That the Court order each defendant to make available to all applicants therefor, for inspection and copying without charge or royalty therefor, all technical data (including FDA drug application materials) in the possession, custody, or control of said defendant, relating in any way to the manufacture, use, sale, or chemical or biological characteristics of ampicillin.

5. That the Court order each defendant to grant to all applicants therefor reasonable-royalty licenses upon reasonable terms, on all United States patents (other than those declared invalid pursuant to

paragraph 3 of this Prayer) relating to any semisynthetic penicillin and on all semisynthetic penicillin technology which such defendant has the right to license.

6. That the Court permanently enjoin each defendant from entering into or maintaining in effect any contract, agreement, understanding, or combination, relating to any pharmaceutical product, the purpose or effect of which is to restrain any party thereto in any of the following ways:

(a) To prohibit it from selling such product in bulk form;

(b) To prohibit it from selling such product generically, without label, or under the label or trade name of its free choice.

7. That the Court order each defendant to sell in bulk form to all applicants therefor, on reasonable terms, ampicillin and any other semisynthetic penicillin which such defendant manufactures or has manufactured or it by another person.

8. That the Court determine and order defendants to pay plaintiff its damages resulting from the aforesaid violations.

9. That the plaintiff have such other and further relief that the nature of the case may require and the Court may deem just and proper.

10. That the plaintiff recover the costs of
this suit.

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