UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA

Plaintiff,

Civil Action

 \mathbf{V} ,

No. 558-68

GLAXO GROUP LIMITED, and : IMPERIAL CHEMICAL INDUSTRIES, : LIMITED, :

Filed: Jan. 25, 1974

Defendants.

Entered: March 1, 1974

FINAL JUDGMENT AS TO IMPERIAL CHEMICAL INDUSTRIES LIMITED

Plaintiff, the United States of America, having filed its complaint herein on March 4, 1968; and defendant Imperial Chemical Industries having consented to the personal jurisdiction of the Court, and the Court having granted plaintiff's several motions for summary judgment respecting the illegality of the challenged combination and agreements, and the Supreme Court of the United States having decreed that defendant Imperial Chemical Industries should be required to sell bulk-form griseofulvin on reasonable and non-discriminatory terms and to license griseofulvin patents at reasonable royalty rates and on reasonable and non-discriminatory terms to all bona fide applicants; and defendant Imperial Chemical Industries and plaintiff having agreed to settle plaintiff's challenge to the validity of U.S. Patent No. 2,900,304 without any adjudication or admission as to the validity or invalidity of said patent and without the taking of any evidence relating thereto; and the Court having considered this matter, it is hereby

ORDERED, ADJUDGED, AND DECREED as follows:

I

As used in this Final Judgment:

(A) "Glaxo" means defendant Glaxo Group Limited;

- (B) "ICI" means defendant Imperial Chemical Industries Limited;
- (C) "Drug" shall be defined as it is in 21 U.S.C.
 § 321(g)(l); and such term shall also include any form of
 such drug (bulk, dosage form, or otherwise);
- (D) "United States sale" means any sale of any drug, made in the United States or made abroad in contemplation of exportation to the United States;
- (E) "Technical data" means know-how, technology, production manuals, drawings, and other information relating to the manufacture, use, or processing of any product, and any material directly or indirectly submitted to the FDA by defendant ICI.
- (F) "Person" means any individual, corporation, association, partnership, or other legal entity.

II

- (A) The Court has jurisdiction of the subject matter of this action and of the parties hereto.
- (B) The defendants have, in violation of Section 1 of the Sherman Act (15 U.S.C. § 1), entered into contracts with their respective purchasers in the United States restricting their freedom to resell the drug griseofulvin in bulk form; and have, in violation of said Section, agreed with each other that defendant ICI should so restrict its purchaser in the United States.

III

The provisions of this Final Judgment applicable to defendant ICI shall apply also to each of its subsidiaries, successors, and assignees, and to their directors, agents, and employees, and to all other persons in active concert or participation with such defendant who receive actual

notice of this Final Judgment by personal service or otherwise.

ΙV

Defendant ICI is enjoined and restrained:

- (A) From entering into, adhering to, maintaining or claiming any rights under any agreement or understanding pursuant to which any party thereto undertakes not to resell, or is limited, prohibited, or restrained in the manner or form in which, or the persons to whom, it resells, any drugs such party purchases in any United States sale.
- (B) From refusing to sell any drug in a United States sale to a purchaser because of the purchaser's refusal to enter into a contract, agreement, or understanding prohibited by Article IV(A).
- (C) From entering into, adhering to, maintaining, or claiming any rights under any agreement or understanding with any other persons providing that any party thereto is to enter into, adhere to, maintain, or claim any rights under any agreement or understanding of the type prohibited by paragraph (A) above.
- (D) From entering into, adhering to, maintaining, or claiming any rights under any agreement or understanding with any of its licensees under any United States patent relating to drugs, which prevents, restrains, or limits any party thereto from selling any drug in bulk form, or otherwise prevents, restrains, or limits any party thereto in its free choice of customers or persons with whom it chooses to deal, provided, however, that this paragraph is not to be construed to prevent defendant ICI from granting exclusive licenses or exclusive distributorships, or to grant licenses limited to particular fields of use

under any United States patent relating to drugs, and provided further that nothing herein shall immunize from the antitrust laws any such license or distributorship, and both parties to the litigation reserve their various rights and powers to challenge or defend any such license or distributorship in any future litigation.

(E) From entering into, adhering to, maintaining, or claiming any rights under any agreement or understanding with any other person providing that any party thereto is to enter into, adhere to, maintain, or claim any rights under any agreement or understanding of the type prohibited by paragraph (D) above.

V

(A) Defendant ICI is ordered, subject to the provisions of this Article, to sell bulk griseofulvin (in each form in which ICI is at the time of sale selling bulk griseofulvin to any person in the United States) on nondiscriminatory terms and prices, to each person in the United States, making a written request therefor for delivery in the United States, in quantities sufficient to meet such person's bona fide stated requirements in the United States; provided, however, that nothing herein shall immunize from the antitrust laws any agreement or understanding with any purchaser restricting the territories in which he may self griseofulvin. ICI shall not be obligated to sell griseofulvin to any person who does not meet reasonable credit requirements. If at the time of any such request, ICI's production is insufficient to meet such request, ICI shall fill such request and other orders, including pre-existing sales obligations, from persons in the United States on a reasonable pro rata allocation basis.

- (B) Defendant ICI is ordered to offer to each person in the United States who makes a written request therefor on reasonable and non-discriminatory terms and (except insofar as provided by Article VI) royalty rates, licenses to make, use, and sell under each United States patent (existing at the time of entry of this Final Judgment or issued within five (5) years from such date of entry) relating to griseofulvin, for human or veterinary use, which ICI owns or has the right to license. Such license shall be for the life of the patent(s), unless the applicant desires a shorter term, and shall be cancellable on 30 days' notice by the licensee.
- (C) Upon receipt of written application for a license under Paragraph (B), above, defendant ICI shall within 30 days advise the applicant in writing of the royalties which it deems reasonable for the patent(s) to which the request pertains. If the applicant rejects the royalties proposed by defendant ICI, and if defendant ICI and applicant are unable to agree upon reasonable royalties or a method of determining the same within 60 days from the date such rejection is communicated in writing to defendant. ICI, the applicant or defendant ICI may, upon notice to the plaintiff and to the other party to the dispute, apply to this Court for the determination of (1) reasonable royalties and (2) such reasonable interim royalties (pending the completion of any such proceeding) as the Court may deem appropriate. In any such proceeding, the burden of proof shall be on defendant to establish the reasonableness of the royalties requested by it. Pending the completion of negotiations or any such proceedings, the applicant shall have the right to make, use, and sell under the patent(s)

to which his application pertains, subject to the payment of reasonable interim royalties. A final Court determination of reasonable royalties shall be applicable to the applicant from the date upon which the applicant requested a license, and after such determination, unless otherwise ordered by the Court in proceedings instituted under this Article, shall be applicable to any other licensee then having or thereafter obtaining the same rights under the same patent(s). If the applicant fails to accept the license, such applicant shall pay the royalties found by the Court to be due to defendant and such costs as the Court may determine to be just and reasonable.

- (D) Nothing herein shall prevent any applicant from attacking, in the aforesaid proceeding or in any other controversy, the validity or scope of any patent or patents nor shall this Final Judgment be construed as imputing any validity or value to any of said patents.
- (E) Defendant ICI is enjoined from making any sale or other disposition of any patent, right or license which deprives it of the power or authority to grant licenses in accordance with the provisions of this Final Judgment, unless the purchaser, transferee, or assignee shall file with this Court, prior to the consummation of said transaction, an undertaking to be bound by its provisions.
- (F) Defendant ICI is prohibited from transferring any assets subject to this Final Judgment, other than goods sold, or otherwise transferred in the ordinary course of business, to any third party ("Takeover Party") that at such time, to ICI's knowledge, proposes to make or has extant any tender offer or takeover bid in respect to the stock or assets of ICI, or has acquired such stock or

assets or has entered into any merger with ICI or agreement therefor, or any affiliate thereof, or to any person acting in concert with or on behalf of any of the foregoing; and ICI is also prohibited from failing to engage in any activity subject to this Final Judgment in order that the Takeover Party, or any affiliate thereof, or any person acting in concert with or on behalf of any of the foregoing, may engage in such activity in lieu of ICI, unless the Takeover Party, affiliate, or person acting in concert therewith or on its behalf, shall first have submitted to the jurisdiction of the Court in this proceeding and consented to be bound by this Final Judgment to the extent provided by law, provided, that ICI shall be free to take any action referred to above, if after 30 days' prior notice to plaintiff of its intent to do so plaintiff has not filed with this Court any objection, and provided further that if plaintiff has filed any such objection ICI shall not take such action until (a) the Takeover Party, affiliate, or person acting in concert therewith or on behalf thereof has submitted to the jurisdiction of the Court in this proceeding and has consented to be bound by this Final Judgment to the extent provided by law, or (b) the Court shall have ruled that ICI may take such action without such submission.

VI

Upon the consent of plaintiff and defendant ICI, without any admission or adjudication as to the validity or invalidity of U.S. Patent No. 2,900,304 or of any other matter
involved in this Article VI, and without the taking of any
evidence relating thereto:

- (A) Defendant ICI will grant each person in the United States making a written request therefor, an irrevocable, royalty-free, non-exclusive, and unrestricted license under U.S. Patent No. 2,900,304, to make, use and sell the subject matter claimed therein. Such license shall be granted by ICI for a term equal to the life of such patent and shall be cancellable on 30 days' notice by the licensee.
- (B) Defendant ICI will grant to each person purchasing under Article V(A) or obtaining a license under Article VI(A) who requests the same, at the reasonable cost of preparing the same, a license to use any and all technical data (existing in written form and in the possession, custody, or control of defendant ICI on the date of the entry of this judgment, or which ICI in the future makes available to any other licensee in the United States) necessary or commercially requisite to make or use (or secure FDA approval to market) griseofulvin by any mode now used by ICI in practicing the patent(s) owned by ICI. Defendant ICI makes no representation as to the efficacy or safety of said data in connection with grades of griseofulvin other than those to which ICI has applied said data. ICI shall have no obligation under this Article VI(B) to furnish technical data to any person unless such person shall have finally accepted a license under the patent to which the technical data pertains. In furnishing any such technical data, ICI shall have the right to require the person receiving the technical data to execute an appropriate agreement forbidding its unauthorized disclosure to third parties, and shall have the right to apply legends to such technical data indicating its proprietary nature.
- (C) In the event that either ICI or Glaxo ceases to sell griseofulvin in bulk form to persons in the United States, ICI

shall make cultures of the micro-organism used by ICI to produce griseofulvin available to each person in the United States,
on reasonable and non-discriminatory terms and upon reasonable compensation therefor, who makes a written request therefor and who intends to use the micro-organism to manufacture
griseofulvin.

VII

For the purpose of securing compliance with this Final Judgment and for no other purpose, and subject to any legally recognized privilege:

- A duly authorized representative of the Department of Justice shall, upon written request of the Attorney General or the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to defendant, made to its principal office, be permitted (1) access in the Inited States during regular office hours of defendant, to inspect and copy any and all books, ledgers, accounts, correspondence, memoranda, and other records, and documents in the possession or under the control of such defendant relating to any of the subject matter contained in this Final Judgment and (2) subject to the reasonable convenience of such defendant, and without restraint or interference from it, to interview officers or employees of such defendant, who may have counsel present, regarding such matters, provided that defendant ICI shall not be obligated to bring to the United States any records or documents or to bring to the United States for the purpose of interview any officer or employee except on order of this Court specifically so providing.
- (B) Upon written request of the Attorney General, or the Assistant Attorney General in charge of the Anti-

trust Division, defendant ICI shall submit such reports in writing with respect to the matters contained in this Final Judgment as may from time to time be requested.

No information obtained by the means provided in this Article VII shall be divulged by any representative of the Department of Justice to any person other than a duly authorized representative of the Executive Branch of the United States Government, except in the course of legal proceedings to which the United States is a party for the purpose of securing compliance with this Final Judgment or as otherwise required by law.

VTTT

The defendant is ordered to file with the plaintiff, on or about June 16 of each year through 1981, a report setting forth the steps which it has taken during the prior year to advise the defendant's appropriate officers, directors, and management personnel cf. its and their obligations under this Final Judgment.

ΙX

Jurisdiction is retained for the purpose of enabling any of the parties to this Final Judgment to apply to this Court at any time for such further orders and directions as may be necessary or appropriate for the construction or modification of any of the provisions thereof, for the enforcement of compliance therewith, and for the punishment of violations thereof.

X

This Final Judgment shall terminate on June 16, 1981, and shall thereafter have no force or effect, except that the provisions of Articles V(B)-(F), VII, and IX shall

continue in full force and effect until the expiration of the last of the United States patents required to be licensed by Article V(B).

XI

Defendants shall pay all taxable costs herein.

XII

It is further ordered that this Final Judgment shall supersede the Final Judgment of June 17, 1971, as amended on August 12, 1971, and March 9, 1972, insofar as that Judgment and the Amendments thereto apply to defendant ICI.

/s/ OLIVER GASCH United States District Judge

Date: March 1, 1974