Trade Regulation Reporter - Trade Cases (1932 - 1992), United States v. Bristol-Myers Co., U.S. District Court, D. District of Columbia, 1982-1 Trade Cases ¶64,597, (Feb. 10, 1982)

United States v. Bristol-Myers Co.

1982-1 Trade Cases ¶64,597. U.S. District Court, D. District of Columbia, M. D. L. Dkt. No. 50; Civ. No. 822-70, Entered February 10, 1982, (Competitive impact statement and other matters filed with settlement: 46 *Federal Register* 52046, 47 *Federal Register* 5484).

Case No. 2088, Antitrust Division, Department of Justice.

Sherman Act

Patent Licensing: Customer Restrictions: Compulsory Bulk Selling: Infringement Suits: Drug Industry: Consent Decree.– A manufacturer of ampicillin and other semisynthetic penicillin was enjoined by a consent decree from restraining the sale of drugs in bulk form or under other than specified trade names. The decree required the defendant to sell drugs in bulk form to qualified buyers, with no across-the-board restrictions on resale. Covenants not to sue for any alleged patent infringement were ordered to be granted under the decree. The manufacturer was also required to grant irrevocable licenses to all comers (other than another defendant manufacturer) at reasonable royalty rates and to furnish special related data. The decree would be in effect for ten years, but provisions concerning patent licensing should continue in effect until expiration of the patent.

For plaintiff: William F. Baxter, Asst. Atty. Gen., Joseph H. Widmar, Roger B. Andewelt, Thomas H. Liddle III, Joseph T. Melillo, and Andrew D. Caverly, Attys., Antitrust Div., Dept. of Justice. **For defendant:** Hughes Hubbard & Reed.

Final Judgment

Richey, D. J.: The plaintiff, United States of America, having filed its complaint herein on March 19, 1970, and defendant, Bristol-Myers Company, having appeared by its attorneys and having filed an answer to such complaint, and the plaintiff and defendant, by their respective attorneys, having consented to the entry of this Final Judgment:

Now, Therefore, before the taking of any testimony, without trial or adjudication of any issue of fact or law herein, without this Final Judgment constituting any evidence against or admission by any party or estoppel in any other action with respect to any issue of fact or law herein, and upon consent of the parties hereto, it is hereby

Ordered, Adjudged and Decreed as follows:

I.

[*Jurisdiction*]

This Court has jurisdiction of the subject matter of this action and of all parties hereto. The complaint states a claim for relief against Bristol-Myers Company under Sections 1 and 2 of the Sherman Act, as amended.

II

[*Definitions*]

As used in this Final Judgment:

(A) “Beecham” means former defendant Beecham Group Limited, with its principal office at Beecham House, Great West Road, Brentford, Middlesex, England; and former defendant Beecham Inc., with its principal office at 65 Industrial South, Clifton, New Jersey 07012.

(B) “Bristol” means defendant Bristol-Myers Company, with its principal office at 345 Park Avenue, New York, New York 10154.

(C) “Ethical pharmaceutical” means any product containing or consisting of any drug (as that term is defined in 21 U. S. C. 321(g)(1)) which, on the effective date of this Final Judgment or when marketed commercially, may be dispensed or sold at retail to an individual consumer only if prescribed by a doctor.

(D) “Dosage form” means any form in which ethical pharmaceuticals are packaged or formulated for use by or administration of their ultimate individual human or animal consumer, and includes, among other things, pills, tablets, capsules, elixirs, syrups, vials, and ampules.

(E) “Bulk form” means the form in which ethical pharmaceuticals are manufactured, prior to their formulation or packaging into dosage form.

(F) “Sterile bulk form” means the bulk form which is suitable for the manufacture of parenteral products.

(G) “Ampicillin” means D-(-)alpha-aminobenzylpenicillin in any form (including the anhydrous forms and trihydrate form), and its salts and esters.

(H) “Semisynthetic penicillin” means any penicillin that is produced from 6-aminopenicillanic acid (“6-APA”) by acylating the 6-amino group or that is produced other than entirely by fermentation processes (with or without precursors), and includes, among other things, ampicillin, ancillin, azidocillin, carbenicillin, cloxacillin, dicloxacillin, flucloxacillin, hetacillin, methicillin, nafcillin, oxacillin, phenbenicillin, phenethicillin, propicillin, and talampicillin, and salts thereof.

(I) “Technical data” means know-how, trade secrets, technology, production manuals, drawings, and other information that relates to the manufacture, use, processing, or securing of FDA approval for the marketing of any product, including (but not limited to) the best mode, method, procedure, and technique thereof known to or used by Bristol.

(J) “Patent” means United States patent, and includes any reissue and any correction of such patent.

(K) “Date of this Final Judgment” means the date of entry of this Final Judgment.

(L)(1) “Semisynthetic penicillin patent” means:

(a) any patent or application for a patent

(i) that claims any one or more of the following: a semisynthetic penicillin; a process or method of making a semisynthetic penicillin (or pharmaceutical composition containing it in combination with any other product); an intermediate (such as 6-APA) or any starting material from which a semisynthetic penicillin is made; a process or method for making an intermediate (or a starting material) from which a semisynthetic penicillin is made; a method of use for (or treatment employing) a semisynthetic penicillin; or a pharmaceutical composition containing a semisynthetic penicillin in combination with any other product; and

(ii) that prior to the date of this Final Judgment Beecham assigned or licensed to Bristol, or Bristol assigned or licensed to Beecham, including (but not limited to) each patent and application for a patent that Beecham and Bristol assigned or licensed to one another pursuant to their agreements of April 2, 1959, August 1, 1960, or January 1, 1967; and

(b) any other patent

(i) that as of July 27, 1981, was owned by, or assigned or licensed to Bristol; and

(ii) that claims any one or more of the things enumerated in Paragraph (L)(1) (a)(i) of this Section II.

(2) The term “semisynthetic penicillin patent” does not include:

(a) United States Patents Nos. 3,192,198, 3,674,776, and Re. 28,744 (all relating to amoxicillin), unless it is agreed by Beecham and Bristol, or finally established in any suit or other proceeding (whether or not Bristol is a party thereto), that such patents are licensed by Beecham to Bristol under their agreement of April 2, 1959; in which case such patents shall be treated in all respects under this Final Judgment as if they were included in the definition of "semisynthetic penicillin patent" under this Paragraph II(L); or

(b) The following United States patents: No. 3,996,236 (relating to sarpicillin), Nos. 3,579,501 and 3,711,471 (both relating to 6-[D-alpha-(3-guanyl-1-ureido) phenylacetamido] pencillanic acid), No. 4,035,381 (relating to furansulfonic acid derivatives of ampicillin and amoxicillin), No. 4,053,360 (relating to a process for making amoxicillin), No. 4,081,441 (relating to anti-pseudomonal penicillins), No. 4,185,015 (relating to sarmoxicillin), No. 4,206,116 (relating to 3,4-dihydroxypiperacillin), No. 4,217,274 (relating to methoxyethoxymethyl esters of various penicillins and semisynthetic penicillins), No. 4,217,275 (relating to a process for using methoxymethyl mesylate as esterifying agent to prepare methoxymethyl esters of penicillins), No. 4,219,495 (relating to methoxymethyl tosylate), No. 4,247,461 (relating to a process for using methoxymethyl tosylate as esterifying agent to prepare methoxymethyl esters of penicillins), No. 4,231,928 (relating to a series of anti-pseudomonal penicillins), No. 4,240,960 (relating to 6-trimethylsilyloxy carbonylamino-penicillanic acid esters, intermediates in making ampicillin and amoxicillin), and No. 4,278,600 (relating to a process for making the product claimed in No. 4,240,960), unless one or more of such patents is assigned or licensed by Bristol to Beecham at any time during a period of five (5) years after the date of this Final Judgment; in which case each patent so licensed or assigned shall be treated in all respects under this Final Judgment as if it were included in the definition of "semisynthetic penicillin patent" under this Paragraph II(L).

(M)(1) "Semisynthetic penicillin technical data" means technical data in the possession, custody, or control of Bristol that it has the right to license at the time of any request therefor made pursuant to this Final Judgment, that is in written form, and that is reasonably necessary or commercially requisite to make, use, process, or secure FDA approval to market any semisynthetic penicillin (or any product containing a semisynthetic penicillin in combination with any other product). The term "semisynthetic penicillin technical data" includes (but is not limited to):

(a) all such technical data that was submitted to the FDA (including, but not limited to, that which relates to securing FDA approval to market any semisynthetic penicillin) by or on behalf of Bristol at or before the date of this Final Judgment; and

(b) all such technical data that relates to using or processing any semisynthetic penicillin, and was known to or used by Bristol at or before the date of this Final Judgment.

(2) Such term does not include

(a) any technical data that relates to--

(i) the manufacture of semisynthetic penicillins (and that was first known to or discovered or developed by Bristol after the date of this Final Judgment),

(ii) the fermentation of penicillin,

(iii) the manufacture of 6-APA,

(iv) the manufacture of any other starting material or starting chemical that (at the time of the request) is reasonably available commercially from a source other than Beecham or Bristol, or

(v) Bristol's amide acceptor process for the manufacture of semisynthetic penicillins; or

(b) any process, product formulation, or intermediate that is defined by the claims of a patent or is disclosed as the invention in a United States patent application pending as of the date of this Final Judgment, if such patent or patent application is not subject to compulsory licensing under Section VI or is expressly excluded from the definition of "semisynthetic penicillin patent" under Paragraph II(L)(2).

(N) “Person” means any individual, corporation, association, partnership, or other business or legal entity. Business or legal entities under common ownership or control, or related as parent or subsidiary, shall be treated as a single person.

(O) “United States sale” means any sale or resale made in the United States.

(P) “Designation” means any United States trademark, trade name, or label, except a trademark, trade name, or label owned by Bristol. The term includes generic labels and established or official names (as those terms are used in 21 U. S. C. Sections 352(e)(2) and 358).

III

[*Applicability*]

(A) The provisions of this Final Judgment shall apply to Bristol; to each of its subsidiaries, successors, and assignees; to their directors, officers, agents, and employees; and to all persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

(B) This Final Judgment shall not apply to activities that occur outside the United States and do not affect the interstate or foreign commerce of the United States. Nothing in this Final Judgment shall constitute or require a grant of any right or rights by Bristol in any foreign jurisdiction or under any foreign patent or trademark or prohibit the enforcement or implementation of any such foreign right or rights.

IV

[*Customer Restrictions*]

(A) Bristol is enjoined and restrained from adhering to, maintaining, or claiming any rights under any existing agreement or understanding, whether or not in the form of a license, that:

(1) restricts, limits, prevents, or prohibits Beecham from making any United States sale of a semisynthetic penicillin or 6-APA in any manner or form, under any designation, or to any person of Beecham's free choice.

(2) authorizes Beecham to make any United States sale of a semisynthetic penicillin or 6-APA in some particular manner or form, under some particular designation, or to some particular person, unless it also permits Beecham to make such sale in any other manner or form, under any and all other designations, or to any other person of Beecham's free choice; or

(3) contains royalty or other fee provisions having the purpose or effect of restricting or limiting Beecham from making any United States sale of a semisynthetic penicillin or 6-APA in any manner or form, under any designation, or to any person of Beecham's free choice.

(B)(1) Nothing in Section IV(A) shall prevent Bristol from maintaining any agreement with Beecham in settlement of a *bona fide* trademark infringement (or other similar) dispute relating to confusion as to the source or origin of a semisynthetic penicillin or 6-APA, pursuant to which agreement Beecham or Bristol (a) agrees not to use, or agrees to limit the use of, any United States trademark involved in the dispute, or (b) agrees to refrain from the practices allegedly giving rise to such confusion. The United States is free to challenge and Bristol is free to defend the lawfulness of any such agreement under the antitrust laws.

(2) Nothing in Section IV(A) shall prevent Bristol from maintaining an exclusive distributorship or an exclusive license, granted to or received from Beecham, under any patent, trademark, trade name, or technical data relating to semisynthetic penicillin or 6-APA, unless such distributorship or license has the purpose or effect of otherwise restricting or limiting Beecham in any way prohibited by Section IV(A) of this Final Judgment.

(C) Bristol shall have one-hundred-twenty (120) days from the date of this Final Judgment within which to bring all existing agreements, understandings, and licenses into compliance with this Section IV. Bristol shall within thirty (30) days thereafter file with this Court an affidavit of such compliance.

V

[*Bulk Sales*]

(A) Bristol is ordered to sell in bulk form to each person, other than Beecham or a person who is a semisynthetic penicillin-bulk customer or licensee of Bristol or Beecham as of the date of this Final Judgment, making a written request therefor for delivery in (or to) the United States, on nondiscriminatory terms and prices, in quantities sufficient to meet such person's *bona fide* stated requirements for sale in the United States:

(1) ampicillin, if Bristol is selling it in the United States at the time of such request; and

(2) any other semisynthetic penicillin--

(a) that, at the time of such request, Bristol is selling in the United States; and

(b) that is claimed in any unexpired semisynthetic penicillin patent.

(B) Bristol is required to make such sales of semisynthetic penicillins pursuant to this Section V:

(1) only in the chemical form in which Bristol is selling such semisynthetic penicillin in the United States at the time of the request; and

(2) in bulk form, and in sterile bulk form, only to the extent that the amount of such required sales of such form of such semisynthetic penicillin in any year does not exceed fifteen percent (15%) of the amount (measured by weight) of such semisynthetic penicillin (for nonparenteral or parenteral use, respectively) that Bristol sold in the United States to any person other than its own subsidiary (which amount was manufactured by Bristol, or for Bristol pursuant to a manufacturing agreement, anywhere in the world) during the calendar year prior to the year in which the request is made.

(C) Bristol shall not be obligated to sell any semisynthetic penicillin in bulk form pursuant to Section V of this Final Judgment to any person who does not:

(1) meet reasonable credit requirements;

(2) give Bristol reasonable advance notification of the quantities it wishes to purchase and the delivery dates it requires;

(3) purchase as a manufacturer or processor for his own use or sale in the United States.

(D) For each semisynthetic penicillin to be sold in bulk form pursuant to this Section V, Bristol shall total all requests therefor made during the first month of each year by all persons, other than Beecham or a person who is a semisynthetic penicillin-bulk customer or licensee of Bristol or Beecham as of the date of this Final Judgment; and, if the total of such requests for any semisynthetic penicillin exceeds the amount Bristol is required to sell pursuant to this Section V, then Bristol shall meet such requests (unless it meets them fully) on a reasonable *pro rata* allocation basis. Bristol shall file all requests made after the first month of each year pursuant to this Section V in the order in which they are received until the limits provided by this Section V are reached (unless it meets such requests fully).

(E) Bristol may take reasonable steps consistent with the purposes of this Final Judgment to protect itself from any risk of product liability (or other similar liability) suits or violation of federal or state statutes or regulations.

(F) Bristol is ordered to sell 6-APA in bulk form during any period that 6-APA is temporarily not reasonably available commercially from a source other than Beecham or Bristol. Bristol shall make such sales on nondiscriminatory terms and prices, to each person making a written request therefor for delivery in the United States and practicing under a license granted pursuant to Section VI hereof, and in quantities sufficient to meet such person's *bona fide* stated requirements for his manufacture and sale of semisynthetic penicillin(s) in the United States. Bristol is not, however, obligated to make such sales to Beecham or any person who is a 6-APA or semisynthetic penicillin-bulk customer or licensee of Bristol or Beecham as of the date of this Final Judgment. The provisions of Paragraphs (B), (C), and (E) of this Section V, applicable to sales of semisynthetic penicillins in bulk form, shall be applicable to sales of 6-APA in bulk form made pursuant to this Paragraph (F), except that the amount of such required sales in any year shall not exceed fifteen percent (15%) of the amount (measured by weight) of 6-APA that Bristol used in making semisynthetic penicillin(s) that it sold in the United States to

any person other than its own subsidiary (which amount of 6-APA was manufactured by Bristol, or for Bristol pursuant to a manufacturing agreement, anywhere in the world) during the calendar year prior to the period in which 6-APA was not so available.

(G) Bristol is ordered to file a statement with this Court, on the date of this Final Judgment, listing each semisynthetic penicillin:

(1) that is claimed in any unexpired semisynthetic penicillin patent, and

(2) that Bristol sold in the United States prior to such date.

VI

[*Infringement Suits*]

(A) Bristol is ordered to grant, without charge (except as provided below), to each person (other than Beecham), who makes a written request therefor, an irrevocable covenant not to sue:

(1) for any alleged infringement of any semisynthetic penicillin patent in connection with the manufacture, use, or sale of ampicillin at any time (whether prior or subsequent to the date of this Final Judgment); or

(2) upon any existing contract to collect, for the use of any patent, royalties accruing after the date of this Final Judgment on sales of ampicillin.

Bristol may charge for such covenant an amount equal to that which it is legally obligated to pay (as of the date of this Final Judgment) and in fact pays any person by reason of the grant of such covenant.

(B)(1) Bristol is ordered to grant, without charge (except as provided in Paragraph VI(B)(2)), to each person (other than Beecham) who makes a written request therefor, an irrevocable covenant not to sue:

(a) for any alleged infringement of United States Patents Nos. 3,192,198, 3,674,776, and Re. 28,744 (all relating to amoxicillin), and any reissue thereof, insofar as Bristol has any rights in such patents; or

(b) to collect, on sales of amoxicillin, any royalties accruing before both conditions (a) and (b) of Paragraph VI(B)(2) are met.

(2) Such a covenant shall be granted without charge unless and until:

(a) it is agreed or finally established, in any suit or other proceeding instituted by Beecham to enforce one or more of the foregoing amoxicillin patents, that such patents are licensed by Beecham to Bristol under this Agreement of April 2, 1959; and

(b) one or more of such patents have been upheld as valid by final, fully-litigated, unappealed decision of any court in the United States on any claim other than a claim brought by Bristol against a person seeking (or entitled to seek) a covenant under Paragraph VI(B).

In the event both conditions (a) and (b) of this Paragraph VI(B)(2) are met, Bristol may then treat the foregoing amoxicillin patents as semisynthetic penicillin patents (as defined in Section II(L) of this Final Judgment), and may, with respect to those of such patents so upheld as valid, charge for such a covenant (or for a license under such patents pursuant to Paragraph VI(C) of this Final Judgment) a reasonable royalty rate. Such a royalty rate shall not exceed the rate at which Bristol is (or would then be) legally obligated to pay (as provided in the above-identified agreement as of the date of this Final Judgment) and in fact pays Beecham on Bristol's own sales of amoxicillin.

(C) Bristol is ordered to grant, to each person (other than Beecham) who makes a written request therefor, an irrevocable license, at a reasonable royalty rate and on reasonable and nondiscriminatory terms, under any, some, or all semisynthetic penicillin patents (as the person making such request may wish) that Bristol has the right to license as of the date of any such request.

(D) Nothing herein shall prevent any applicant from attacking the validity or scope of any patent or patents to be licensed by Bristol pursuant to this Section VI of this Final Judgment; nor shall this Final Judgment be construed as imputing any validity or invalidity to any of such patents.

(E) Bristol is ordered to file with this Court, on the date of this Final Judgment, a statement listing each semisynthetic penicillin patent that is owned by or assigned or licensed to Bristol and that Bristol has the right to license or sublicense.

VII

[*Licensing*]

(A) Bristol is ordered to furnish to each person, other than Beecham, making a *bona fide* written request therefor, and to license such person to use, in connection with the manufacture, use, or sale of semisynthetic penicillins in the United States, or with the practice of semisynthetic penicillin patents in the United States, any, some, or all semisynthetic penicillin technical data (as the person making such request may wish) that relates to:

(1) ampicillin;

(2) the commercial exploitation of only the semisynthetic penicillin patents licensed to such person pursuant to Section VI of this Final Judgment;

(3) using, bulk processing (including the conversion of semisynthetic penicillins from bulk form to dosage form), or securing FDA approval to market any semisynthetic penicillin claimed in a semisynthetic penicillin patent:

(a) that such person makes or has made under a license granted pursuant to Section VI of this Final Judgment;

(b) that such person purchases from Bristol pursuant to Section V of this Final Judgment, from a licensee of Bristol or Beecham for such semisynthetic penicillin, or from a person practicing under a license for such semisynthetic penicillin granted pursuant to Section VI hereof.

There shall be no upper limit on the number of requests made under this Section VII.

(B) The charge for such semisynthetic penicillin technical data shall be as follows:

(1) for semisynthetic penicillin technical data in the public domain and for semisynthetic penicillin technical data (whether or not in the public domain) used for manufacturing, bulk processing, using, or securing FDA approval to market ampicillin:

(a) the actual out-of-pocket cost to Bristol of reproducing the data supplied; and

(b) a royalty or fee equal to that which Bristol is legally obligated to pay (as of the date of this Final Judgment) and in fact pays to any person other than Beecham, by reason of the grant of a license thereof;

(2) for other semisynthetic penicillin technical data not in the public domain: a reasonable royalty for its use other than in connection with ampicillin, such royalty to terminate with respect to any such technical data that falls into the public domain for any reason other than the wrongful act of a licensee.

(C) In furnishing and licensing semisynthetic penicillin technical data pursuant to this Section VII, Bristol may:

(1) require the person receiving such technical data to execute an appropriate agreement forbidding its disclosure to any third party without Bristol's consent, so long as such technical data is not otherwise in the public domain; but such person may disclose such technical data to any third party who agrees to be bound by such agreement, and who manufactures or processes any semisynthetic penicillin solely for a licensee or bulk purchaser under this Final Judgment; and

(2) apply legends to such technical data indicating its proprietary nature.

VIII

[*Royalties*]

(A) Upon receipt of a written application for a license under Section VI or Section VII above, Bristol shall within thirty (30) days advise the applicant in writing of the royalties which it deems reasonable for a license of patent(s) or technical data requested and the conditions and terms thereof, if any. If the applicant rejects the royalties, conditions, or terms proposed by Bristol, and if Bristol and the applicant are unable to agree upon reasonable conditions, terms, or royalties, or upon a method of determining reasonable royalties (including arbitration), within sixty (60) days from the date such rejection is communicated in writing to Bristol, the applicant or Bristol may, upon notice to plaintiff and to the other party to the dispute, apply to the Court for (1) the determination of reasonable conditions, terms, and royalties and (2) a preliminary determination of such reasonable interim royalties on patents as the Court may deem appropriate pending the completion of such proceeding. In any such proceeding, the burden of proof shall be upon Bristol to establish that the conditions, terms, and royalties which it proposes are reasonable. Pending the completion of negotiations or any such proceedings, the applicant shall have a provisional license of the scope provided in his application for a license to practice the patent(s) to which his application pertains, subject to the payment to Bristol of reasonable interim royalties on such patent(s); provided, however, that no provisional license shall contravene any of the provisions of this Final Judgment. A final determination of reasonable royalties, or that no royalties are to be charged, for practicing the patent(s) shall be applicable from the date upon which the applicant requested a license. Such determination shall, unless otherwise ordered by the Court in proceedings instituted under this Section VIII, be applicable thereafter to any other licensee then having or thereafter obtaining the same rights under the same patent(s) or technical data. If the applicant fails to accept a patent license after final determination by the Court of the amount of reasonable royalties with respect thereto in a proceeding under this Section VIII, such applicant shall pay only the interim royalties that may be found by the Court to be due to Bristol with respect thereto and such costs as may be determined by the Court to be just and reasonable.

(B) The licenses granted by Bristol pursuant to Sections VI and VII of this Final Judgment shall be without any condition or limitation, except as provided herein, and shall, with respect to patent(s), be granted for a term equal to the life of the licensed patent(s). Such licenses may be cancelled by the licensee upon thirty (30) days' written notice to Bristol.

(C) Bristol is enjoined from conditioning the grant of any license under either Section VI or VII of this Final Judgment, or the furnishing of semisynthetic penicillin technical data, upon the grant or acceptance by the licensee of a license under any other United States or foreign patent, or of rights relating to any other technical data.

(D) Reasonable provisions may be made, in the licenses granted by Bristol pursuant to Section VI or VII of this Final Judgment, for periodic royalty reports by the licensee, including such reports as may be necessary to allow Bristol to fulfill its obligations, if any, to third parties, and for inspection of the relevant books and records of the licensee by an independent auditor or other person acceptable to both licensor and licensee (or, in the absence of agreement, a person selected by this Court), who shall report to Bristol only the amount of the royalty or other charge due and payable.

IX

[*Licensee Obligations*]

(A) Bristol is enjoined and restrained from making any sale or other disposition of any right, patent, technical data, or license which deprives it of the power or authority to sell semisynthetic penicillins in bulk form, to grant licenses to practice semisynthetic penicillin patents, or to grant licenses to use semisynthetic penicillin technical data in accordance with the provisions of this Final Judgment, unless the purchaser, transferee, licensee, or assignee of such right, patent, technical data, or license shall file with this Court, prior to the consummation of any such sale or other disposition, an undertaking to be bound by the provisions of, and to assume the obligations of Bristol under, this Final Judgment with respect to such right, patent, technical data, or license sold or disposed of thereto.

(B) Bristol is enjoined and restrained from:

(1) 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 that, according to Bristol's knowledge, proposes to make or has extant any tender offer or takeover bid in respect to the stock and assets of Bristol; has acquired such stock or assets; or has entered into any merger with Bristol or agreement therefor;

(2) failing or declining to engage in any activity subject to this Final Judgment in order that a third party (as referred to in Paragraph (B)(1) of this section) may engage in such activity in lieu of Bristol, unless such third party shall first have submitted to the jurisdiction of this Court and consented to be bound by this Final Judgment to the extent provided by law. Provided, however, that Bristol shall be free to take any action prohibited by this Section IX, if after thirty (30) days' prior notice to plaintiff of Bristol's intent to take any such action plaintiff has not filed any objection thereto with this Court, and provided further that, if plaintiff has filed any such objection, Bristol shall not take such action until (a) such third party has submitted to the jurisdiction of the Court and has consented to be bound by this Final Judgment to the extent provided by law, or (b) the Court shall have ruled that Bristol may take such action without such submission.

X

[*Notice*]

Within ninety (90) days of the date of this Final Judgment:

(A) Bristol is ordered and directed to publish notice of the availability of (1) semisynthetic penicillins for purchase in bulk form pursuant to Section V of this Final Judgment, and (2) licenses under semisynthetic penicillin patents and technical data pursuant to Sections VI and VII of this Final Judgment, in one issue of *Chemical & Engineering News* (published by American Chemical Society) and *Chemical Week* (published by McGraw-Hill, Inc.), and to publish notice of the availability of such licenses in one issue of the Official Gazette of the United States Patent and Trademark Office; and

(B) Bristol is ordered and directed to give notice in writing of such availability to each person who since January 1, 1965, has indicated in writing to Bristol an interest in purchasing any semisynthetic penicillin in bulk form in the United States or obtaining a license under any semisynthetic penicillin patent.

XI

[*Compliance*]

(A) For the purpose of securing compliance or determining whether there has been compliance with this Final Judgment, and subject to any legally recognized privilege, any 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 Bristol made to its principal office, be permitted:

(1) access, during regular office hours of Bristol, to all books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or custody or under the control of Bristol relating to any of the subject matter contained in this Final Judgment (including all patent, trademark, trade name, or technical data licenses relating to ethical pharmaceuticals, whether or not containing provisions prohibited by this Final Judgment); and

(2) subject to the reasonable convenience of Bristol, and without restraint or interference from it, to interview officers, directors, agents, partners, or employees of Bristol, who may have counsel present, regarding any such matters; provided, however, that Bristol 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, director, agent, partner, 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 Antitrust Division, made for the purpose of securing compliance or determining whether there has been compliance with

this Final Judgment, Bristol shall submit such reports in writing with respect to matters contained in this Final Judgment as may be requested.

(C) No information obtained by the means provided in this Section XI 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, except in the course of legal proceedings to which the United States is a party, or for the purpose of securing compliance or determining whether there has been compliance with this Final Judgment, or for federal law enforcement purposes by the United States, or as otherwise required by law.

(D) If, at the time information or documents are furnished by Bristol to plaintiff, Bristol represents and identifies in writing the material in any such information or documents for which a claim of protection may be asserted under Rule 26(c)(7) of the Federal Rules of Civil Procedure, and Bristol marks the appropriate portion of each pertinent page of such material, “Subject to claim of protection under Rule 26(c) (7) of the Federal Rules of Civil Procedure,” then ten (10) days' notice shall be given by plaintiff to Bristol prior to divulging such material in any legal proceeding (other than a Grand Jury proceeding) to which Bristol is not a party.

XII

[*Retention of Jurisdiction*]

Jurisdiction is retained by this Court 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, or for the punishment of violations thereof.

XIII

[*Term*]

(A) Except as provided in Paragraph (B) of this Section XIII, this Final Judgment shall terminate ten (10) years after the date of its entry, and shall thereafter have no force or effect.

(B)(1) The provisions of Section VI shall continue in effect until the expiration of the patents required to be licensed thereunder.

(2) The obligation to grant licenses to use semisynthetic penicillin technical data pursuant to the provisions of Section VII shall continue in effect until the expiration of Bristol's obligation to license the patents or to sell the semisynthetic penicillins in bulk form to which the licensed semisynthetic penicillin technical data relates.

(C) The compulsory bulk selling provisions of Section V shall continue in effect, as to 6-APA and each semisynthetic penicillin (other than ampicillin) required to be sold in bulk form thereunder, until the expiration of the last of the patents owned by or assigned or licensed to Bristol which claims 6-APA or that semisynthetic penicillin, or five (5) years after the date of this Final Judgment, whichever is sooner.

(D) The compulsory bulk selling provisions of Section V, as to ampicillin, shall continue in effect for five (5) years after the date of this Final Judgment.

XIV

[*Public Interest*]

Entry of this Final Judgment is in the public interest.