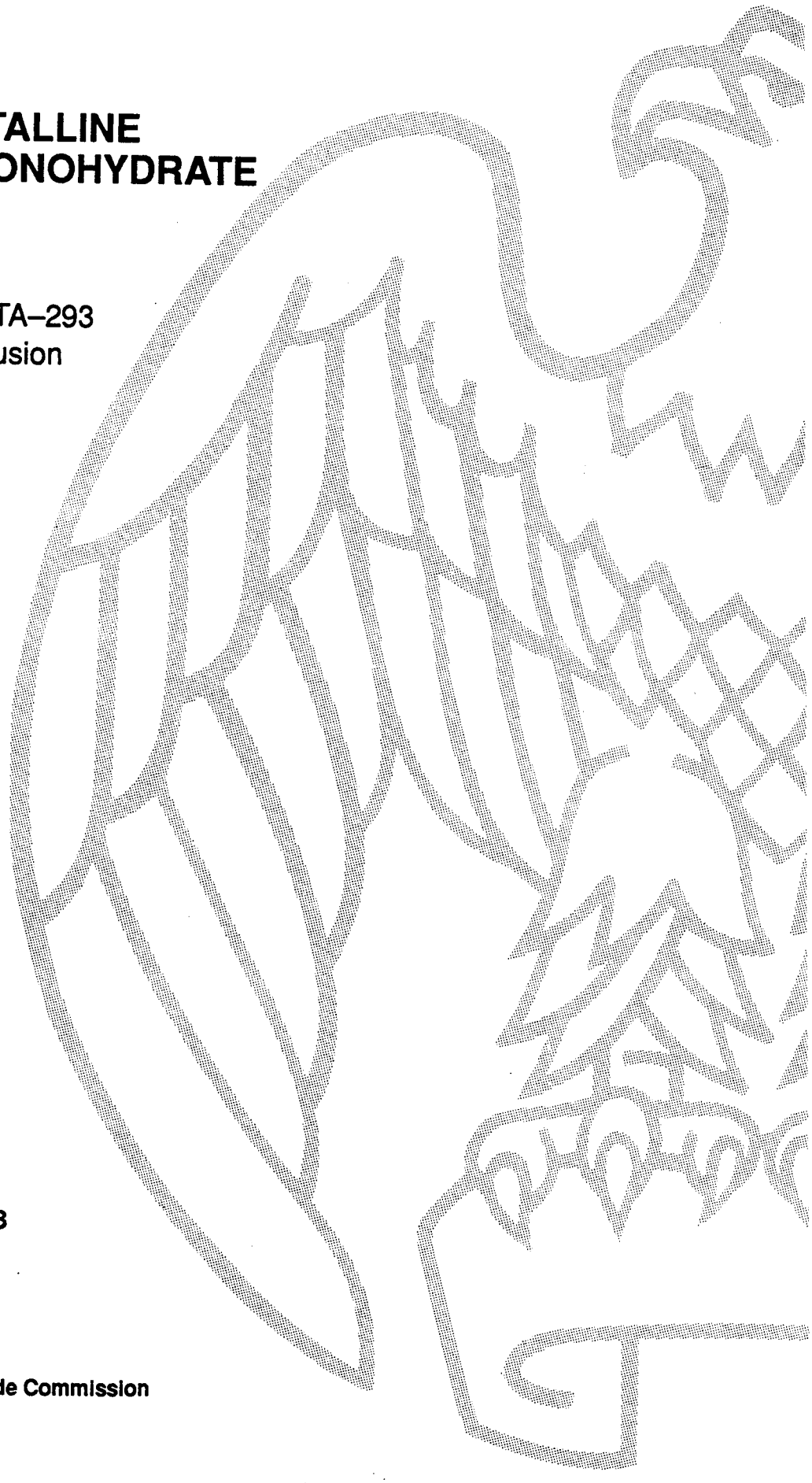
In the Matter of

CERTAIN CRYSTALLINE CEFADROXIL MONOHYDRATE

Investigation No. 337–TA–293
Temporary limited exclusion order

(Commission Decision of January 10, 1990)



USITC PUBLICATION 2373

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United States International Trade Commission
Washington, DC 20436

UNITED STATES INTERNATIONAL TRADE COMMISSION

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN CRYSTALLINE CEFADROXIL MONOHYDRATE	)	Investigation No. 337-TA-293

NOTICE OF ISSUANCE OF A TEMPORARY LIMITED EXCLUSION ORDER AND TEMPORARY CEASE AND DESIST ORDERS AND AMENDMENT OF THE NOTICE OF INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Commission has issued a temporary limited exclusion order and temporary cease and desist orders and has amended the notice of investigation in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Marc A. Bernstein, Office of the General Counsel, U.S. International Trade Commission, telephone 202-252-1087.

SUPPLEMENTARY INFORMATION: The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337), as amended by the Omnibus Trade and Competitiveness Act of 1988, Pub. L. 100-418 (Aug. 23, 1988), and in sections 210.24 and 210.58 of the Commission's Interim Rules of Practice and Procedure (19 C.F.R. §§ 210.24, 210.58).

On February 1, 1989, Bristol-Myers Company (since renamed Bristol-Myers Squibb Company) filed a complaint and a motion for temporary relief with the Commission alleging violations of section 337 in the importation and sale of certain crystalline cefadroxil monohydrate. The complaint alleged infringement of claim 1 of U.S. Letters Patent 4,504,657 owned by Bristol-Myers.

Pursuant to Commission interim rule 210.24(e)(8), the Commission provisionally accepted Bristol-Myers's motion for temporary relief on March 8, 1989. The Commission also instituted an investigation into the allegations of Bristol-Myers's complaint and published a notice of investigation in the Federal Register. 54 F.R. 10740 (March 15, 1989). The notice named the following respondents: (1) Biocraft Laboratories, Inc. of Elmwood Park, N.J. (2) Gema, S.A. of Barcelona, Spain; (3) Kalipharma, Inc. of Elizabeth, N.J.; (4) Purepac Pharmaceutical Co. of Elizabeth, N.J.; (5) Istituto Biochimico Italiano Industria Giovanni Lorenzini S.p.A. of Milan, Italy; and (6) Institut Biochimique, S.A. of Massagno, Switzerland.

On May 13, 1989, the presiding administrative law judge ("ALJ") issued an initial determination ("ID") denying Bristol-Myers's motion for temporary relief. On June 13, 1989, the Commission issued a determination refusing to modify or vacate the ID insofar as it denied that motion. Bristol-Myers appealed the Commission's determination to the United States Court of Appeals for the Federal Circuit. On December 8, 1989, the Federal Circuit issued a decision reversing the Commission's determination. Bristol-Myers Co. v. USITC, App. No. 89-1530 (Fed. Cir. Dec. 8, 1989). The Federal Circuit's mandate issued on December 29, 1989. The Federal Circuit determined that Bristol-Myers had established that there is reason to believe that there is a violation of section 337 in the importation, sale for importation, or sale in the United States of the accused crystalline cefadroxil monohydrate, and that the public interest supports issuance of temporary relief. The Federal Circuit's decision effectively directed the Commission to grant temporary relief to Bristol-Myers.

Immediately after issuance of the Federal Circuit's decision, the Commission solicited and received from the parties comments on the issues of temporary relief and bonding not resolved by the decision. Having considered the Federal Circuit's decision, the parties' comments, and the record in this investigation, the Commission determined that a temporary limited exclusion order and temporary cease and desist orders directed to all U.S. respondents are the appropriate form of temporary relief. The issuance of temporary relief is not subject to the posting of bond by complainant. The Commission determined that the public interest factors enumerated in 19 U.S.C. § 1337(e) and (f) do not preclude the issuance of temporary relief. The Commission further determined that respondents' bond under the temporary limited exclusion order and the temporary cease and desist orders shall be in the amount of sixty-eight (68) percent of the entered value of the imported articles.

Pursuant to a motion by complainant, the Commission also determined to amend the notice of investigation in this investigation to reflect complainant's change of name from "Bristol-Myers Company" to "Bristol-Myers Squibb Company."

Copies of all nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone 202-252-1000. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-252-1810.

By order of the Commission.

Kenneth R. Mason
Secretary

Issued: January 10, 1990

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN CRYSTALLINE CEFADROXIL MONOHYDRATE	)	Investigation No. 337-TA-293

ORDER

On February 1, 1989, Bristol-Myers Company (since renamed Bristol-Myers Squibb Company) filed a complaint and a motion for temporary relief with the Commission alleging violations of section 337 in the importation and sale of certain crystalline cefadroxil monohydrate. The complaint alleged infringement of claim 1 of U.S. Letters Patent 4,504,657 owned by Bristol-Myers.

Pursuant to Commission interim rule 210.24(e)(8), the Commission provisionally accepted Bristol-Myers's motion for temporary relief at the Commission meeting on March 8, 1989. The Commission also instituted an investigation into the allegations of Bristol-Myers's complaint and published a notice of investigation in the Federal Register. 54 F.R. 10740 (March 15, 1989). The notice named the following respondents: (1) Biocraft Laboratories, Inc. of Elmwood Park, N.J. (2) Gema, S.A. of Barcelona, Spain; (3) Kalipharma, Inc. of Elizabeth, N.J.; (4) Purepac Pharmaceutical Co. of Elizabeth, N.J.; (5) Istituto Biochimico Italiano Industria Giovanni Lorenzini S.p.A. of Milan, Italy; and (6) Institut Biochimique, S.A. of Massagno, Switzerland.

On May 13, 1989, the presiding administrative law judge ("ALJ") issued an initial determination ("ID") denying Bristol-Myers's motion for temporary relief. On June 13, 1989, the Commission issued a determination

refusing to modify or vacate the ID insofar as it denied that motion. Bristol-Myers appealed the Commission's denial to the United States Court of Appeals for the Federal Circuit. On December 8, 1989, the Federal Circuit issued a decision reversing the Commission's determination. Bristol-Myers Co. v. USITC, App. No. 89-1530 (Fed. Cir. Dec. 8, 1989). The Federal Circuit's mandate issued on December 29, 1989. The Federal Circuit determined that Bristol-Myers had established that there is reason to believe that there is a violation of section 337 in the importation, sale for importation, or sale in the United States of the accused crystalline cefadroxil monohydrate, and that the public interest supports issuance of temporary relief. The Federal Circuit's decision effectively directed the Commission to grant temporary relief to Bristol-Myers.

Immediately after issuance of the Federal Circuit's decision, the Commission solicited and received from the parties comments on the issues of temporary relief and bonding not resolved by the decision.

Having considered the Federal Circuit's decision, the parties' comments, and the record in this investigation, the Commission has determined that a temporary limited exclusion order and temporary cease and desist orders directed to all U.S. respondents are the appropriate form of temporary relief. The issuance of temporary relief is not subject to a posting of bond by complainant. The Commission has determined that the public interest factors enumerated in 19 U.S.C. § 1337(e) and (f) do not preclude the issuance of temporary relief. The Commission has further determined that respondents' bond during the period of Presidential review, and under the temporary limited exclusion order and the temporary cease and desist orders, if they are not disapproved by the President, shall be in the

amount of sixty-eight (68) percent of the entered value of the imported articles.

The Commission has also determined to amend the notice of investigation in this investigation to reflect complainant's change of name from "Bristol-Myers Company" to "Bristol-Myers Squibb Company."

Accordingly, it is hereby ORDERED THAT --

1. Crystalline cefadroxil monohydrate capsules and crystalline cefadroxil monohydrate bulk powder manufactured abroad by Gema, S.A. of Spain; Istituto Biochimico Italiano Industria Giovanni Lorenzini S.p.A. of Italy; and Institut Biochimique, S.A. of Switzerland; or any of their affiliated companies, parents, subsidiaries, licensees, contractors, or other related entities, or their successors or assigns, that infringe claim 1 of U.S. Letters Patent 4,504,657, are excluded from entry into the United States during the pendency of USITC Investigation No. 337-TA-293, except under license of the patent owner.

2. In accordance with 19 U.S.C. § 1337(1), the provisions of this Order do not apply to crystalline cefadroxil monohydrate capsules or bulk powder imported by or for the United States.

3. The articles identified in paragraph (1) of this Order are entitled to entry into the United States under bond in the amount of sixty-eight (68) percent of their entered value until the day after the Commission issues its final determination in Investigation No. 337-TA-293, unless, pursuant to 19 U.S.C. § 1337(j)(3), the President notifies the Commission within 60 days after the date he receives this Order, that he disapproves this Order.

4. The attached cease and desist orders are issued to Biocraft Laboratories, Inc., Kalipharma, Inc., and Purepac Pharmaceutical Co.

5. Paragraph 3(a) of the "Scope of Investigation" section of the notice of investigation in this investigation is amended to read as follows:

   (a) The complainant is--

   Bristol-Myers Squibb Company
   345 Park Avenue
   New York, N.Y. 10154

6. The Commission may amend this Order in accordance with the procedure described in section 211.57 of the Commission's Interim Rules of Practice and Procedure, 19 C.F.R. § 211.57.

7. A copy of this Order shall be served upon each party of record in this investigation and upon the Department of Health and Human Services, the Department of Justice, and the Federal Trade Commission.

8. Notice of this Order shall be published in the Federal Register.

By order of the Commission.

Kenneth R. Mason
Secretary

Issued: January 10, 1990

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN CRYSTALLINE CEFADROXIL MONOHYDRATE	)	Investigation No. 337-TA-293

ORDER TO CEASE AND DESIST

IT IS HEREBY ORDERED THAT Kalipharma, Inc., 200 Elmora Avenue, Elizabeth, New Jersey 07207, cease and desist from marketing, distributing, offering for sale, selling, or otherwise transferring in the United States certain imported crystalline cefadroxil monohydrate during the pendency of USITC Investigation No. 337-TA-293.

I

(Definitions)

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainant" shall mean Bristol-Myers Squibb Company, New York, N.Y.

(C) "Respondent" shall mean Kalipharma, Inc., 200 Elmora Avenue, Elizabeth, New Jersey 07207.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than the above Respondent or its majority owned and/or controlled subsidiaries, their successors, or assigns.

(E) "United States" shall mean the fifty states, the District of Columbia, and Puerto Rico.

II

(Applicability)

The provisions of this Order shall apply to Respondent and to its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and/or majority owned business entities, successors, and assigns.

III

(Conduct Prohibited)

Respondent shall not market, distribute, offer for sale, sell, or otherwise transfer in the United States imported crystalline cefadroxil monohydrate that infringes claim 1 of U.S. Letters Patent 4,504,657, except under license of the patent owner.

IV

(Conduct Permitted)

Notwithstanding any other provisions of this Order, specific conduct otherwise prohibited by the terms of this Order, shall be permitted if, in a written instrument, such specific conduct is licensed or authorized by Complainant or related to the importation or sale of crystalline cefadroxil monohydrate thereof by or for the United States.

V

(Reporting)

For purposes of this reporting requirement, the reporting period shall cover the period from the date of this Order to March 16, 1990. This reporting requirement shall continue in force until the day after the Commission issues its final determination in Investigation No. 337-TA-293, unless, pursuant to subsection (j)(3) of section 337 of the Tariff Act of 1930, the President notifies the Commission within 60 days after the date he receives this Order, that he disapproves this Order.

Any failure to report shall constitute a violation of this Order.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission the following:

(A) Its sales or other transfers in the United States, measured in capsules of crystalline cefadroxil monohydrate, and in grams of bulk powder of crystalline cefadroxil monohydrate, for the period ending on March 16, 1990; and

(B) All contracts, whether written or oral, entered into during the period ending on March 16, 1990, to sell or otherwise transfer capsules or bulk powder of crystalline cefadroxil monohydrate.

In connection with the sales or other transfers referred to in paragraphs (A) and (B) above, Respondent shall provide the Commission with two copies of all invoices, delivery orders, bills of lading, and other documents concerning the importation or sale in question. Such copies shall be attached to the reports required by paragraphs (A) and (B) above.

VI

(Compliance and Inspection)

(A) For the purposes of securing compliance with this Order, Respondent shall retain any and all records relating to the sale in the United States of crystalline cefadroxil monohydrate referred to in paragraphs (V)(A) and (V)(B) above made and received in the usual and ordinary course of its business, whether in detail or in summary form, for a period of two (2) years from the close of the fiscal year to which they pertain.

(B) For the purpose of determining or securing compliance with this Order and for no other purpose, and subject to any privilege recognized by Federal Courts of the United States, Respondent shall furnish or otherwise make available for inspection and copying to duly authorized representatives of the Commission, and in the presence of counsel or other representative if Respondent so chooses, upon reasonable written notice by the Commission or its staff, all books, ledgers, accounts, correspondence, memoranda, financial reports, and other records or documents in its possession or control for the purpose of verifying any matter or statement contained in the reports required under section V of this Order.

VII

(Service of Cease and Desist Order)

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the date of issuance of this Order, a copy of the Order upon each of its respective officers, directors, managing agents, agents and employees who have any responsibility for the

marketing, distribution, or sale of imported crystalline cefadroxil monohydrate in the United States.

(B) Serve, within fifteen (15) days after the succession of any of the persons referred to in paragraph VII(A), a copy of this Order upon each successor.

(C) Maintain such records as will show the name, title, and address of each person described in paragraph VII(A) and (B) above upon whom this Order has been served, together with the date on which service was made.

(D) The obligations set forth in paragraphs VII (B) and (C) above shall remain in effect until the day after the Commission issues its final determination in Investigation No. 337-TA-293, unless, pursuant to subsection (j)(3) of section 337 of the Tariff Act of 1930, the President notifies the Commission within 60 days after the date he receives this Order, that he disapproves this Order.

VIII

(Confidentiality)

Information obtained by the means provided for in sections V and VI of this Order will be made available only to the Commission and its authorized representatives, will be entitled to confidential treatment, and will not be divulged by any authorized representative of the Commission to any person other than duly authorized representatives of the Commission, except as may be required in the course of securing compliance with this Order, or as otherwise required by law. Disclosure hereunder will not be made by the Commission without ten (10) days prior notice in writing to Respondent.

IX

(Enforcement)

Violation of this Order may result in any of the actions specified in section 211.56 of the Commission's Interim Rules of Practice and Procedure, 19 C.F.R. § 211.56, including an action for civil penalties in accordance with section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), and such other action as the Commission may deem appropriate. In determining whether Respondent is in violation of this Order, the Commission may infer facts adverse to Respondent if Respondent fails to provide adequate or timely information as required by this Order.

X

(Modification)

This Order may be modified by the Commission on its own motion or upon motion by any person pursuant to section 211.57 of the Commission's Interim Rules of Practice and Procedure, 19 C.F.R. § 211.57.

XI

(Bonding)

With respect to crystalline cefadroxil monohydrate imported prior to January 10, 1990, the conduct prohibited by paragraph III of this Order may be continued during the period in which this order is in effect subject to Respondent posting a bond in the amount of sixty-eight (68) percent of the entered value of crystalline cefadroxil monohydrate capsules or bulk powder in question. This bond provision does not apply to conduct which is otherwise permitted by paragraph IV of this Order. Crystalline cefadroxil

monohydrate capsules or bulk powder imported on or after January 10, 1990, are subject to the entry bond as set forth in the limited temporary exclusion order issued by the Commission on January 10, 1990, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders (53 Fed. Reg. 49133-34 (Dec. 6, 1988)).

The bond and any accompanying documentation is to be provided to and approved by the Commission prior to the commencement of conduct which is otherwise prohibited by paragraph III of this Order.

The bond is to be forfeited in the event that the President approves, or does not disapprove within the Presidential review period, the Commission's Orders of January 10, 1990, or any subsequent final order issued after the completion of Investigation No. 337-TA-293, unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or unless Respondent exports the products subject to this bond or destroys them and provides certification to that effect satisfactory to the Commission.

The bond is to be released in the event the President disapproves this Order and no subsequent order is issued by the Commission and approved, or not disapproved, by the President, upon service on Respondent of an Order issued by the Commission based upon application therefor made by Respondent to the Commission.

By Order of the Commission.

Kenneth R. Mason

Secretary

Issued: January 10, 1990

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN CRYSTALLINE CEFADROXIL MONOHYDRATE	)	Investigation No. 337-TA-293

ORDER TO CEASE AND DESIST

IT IS HEREBY ORDERED THAT Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, New Jersey 07407, cease and desist from marketing, distributing, offering for sale, selling, or otherwise transferring in the United States certain imported crystalline cefadroxil monohydrate during the pendency of USITC Investigation No. 337-TA-293.

I

(Definitions)

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainant" shall mean Bristol-Myers Squibb Company, New York, N.Y.

(C) "Respondent" shall mean Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, New Jersey 07407.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than the above Respondent or its majority owned and/or controlled subsidiaries, their successors, or assigns.

(E) "United States" shall mean the fifty states, the District of Columbia, and Puerto Rico.

II

(Applicability)

The provisions of this Order shall apply to Respondent and to its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and/or majority owned business entities, successors, and assigns.

III

(Conduct Prohibited)

Respondent shall not market, distribute, offer for sale, sell, or otherwise transfer in the United States imported crystalline cefadroxil monohydrate that infringes claim 1 of U.S. Letters Patent 4,504,657, except under license of the patent owner.

IV

(Conduct Permitted)

Notwithstanding any other provisions of this Order, specific conduct otherwise prohibited by the terms of this Order, shall be permitted if, in a written instrument, such specific conduct is licensed or authorized by Complainant or related to the importation or sale of crystalline cefadroxil monohydrate thereof by or for the United States.

V

(Reporting)

For purposes of this reporting requirement, the reporting period shall cover the period from the date of this Order to March 16, 1990. This reporting requirement shall continue in force until the day after the Commission issues its final determination in Investigation No. 337-TA-293, unless, pursuant to subsection (j)(3) of section 337 of the Tariff Act of 1930, the President notifies the Commission within 60 days after the date he receives this Order, that he disapproves this Order.

Any failure to report shall constitute a violation of this Order.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission the following:

(A) Its sales or other transfers in the United States, measured in capsules of crystalline cefadroxil monohydrate, and in grams of bulk powder of crystalline cefadroxil monohydrate, for the period ending on March 16, 1990; and

(B) All contracts, whether written or oral, entered into during the period ending on March 16, 1990, to sell or otherwise transfer capsules or bulk powder of crystalline cefadroxil monohydrate.

In connection with the sales or other transfers referred to in paragraphs (A) and (B) above, Respondent shall provide the Commission with two copies of all invoices, delivery orders, bills of lading, and other documents concerning the importation or sale in question. Such copies shall be attached to the reports required by paragraphs (A) and (B) above.

VI

(Compliance and Inspection)

(A) For the purposes of securing compliance with this Order, Respondent shall retain any and all records relating to the sale in the United States of crystalline cefadroxil monohydrate referred to in paragraphs (V)(A) and (V)(B) above made and received in the usual and ordinary course of its business, whether in detail or in summary form, for a period of two (2) years from the close of the fiscal year to which they pertain.

(B) For the purpose of determining or securing compliance with this Order and for no other purpose, and subject to any privilege recognized by Federal Courts of the United States, Respondent shall furnish or otherwise make available for inspection and copying to duly authorized representatives of the Commission, and in the presence of counsel or other representative if Respondent so chooses, upon reasonable written notice by the Commission or its staff, all books, ledgers, accounts, correspondence, memoranda, financial reports, and other records or documents in its possession or control for the purpose of verifying any matter or statement contained in the reports required under section V of this Order.

VII

(Service of Cease and Desist Order)

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the date of issuance of this Order, a copy of the Order upon each of its respective officers, directors, managing agents, agents and employees who have any responsibility for the

marketing, distribution, or sale of imported crystalline cefadroxil monohydrate in the United States.

(B) Serve, within fifteen (15) days after the succession of any of the persons referred to in paragraph VII(A), a copy of this Order upon each successor.

(C) Maintain such records as will show the name, title, and address of each person described in paragraph VII(A) and (B) above upon whom this Order has been served, together with the date on which service was made.

(D) The obligations set forth in paragraphs VII (B) and (C) above shall remain in effect until the day after the Commission issues its final determination in Investigation No. 337-TA-293, unless, pursuant to subsection (j)(3) of section 337 of the Tariff Act of 1930, the President notifies the Commission within 60 days after the date he receives this Order, that he disapproves this Order.

VIII

(Confidentiality)

Information obtained by the means provided for in sections V and VI of this Order will be made available only to the Commission and its authorized representatives, will be entitled to confidential treatment, and will not be divulged by any authorized representative of the Commission to any person other than duly authorized representatives of the Commission, except as may be required in the course of securing compliance with this Order, or as otherwise required by law. Disclosure hereunder will not be made by the Commission without ten (10) days prior notice in writing to Respondent.

IX

(Enforcement)

Violation of this Order may result in any of the actions specified in section 211.56 of the Commission's Interim Rules of Practice and Procedure, 19 C.F.R. § 211.56, including an action for civil penalties in accordance with section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), and such other action as the Commission may deem appropriate. In determining whether Respondent is in violation of this Order, the Commission may infer facts adverse to Respondent if Respondent fails to provide adequate or timely information as required by this Order.

X

(Modification)

This Order may be modified by the Commission on its own motion or upon motion by any person pursuant to section 211.57 of the Commission's Interim Rules of Practice and Procedure, 19 C.F.R. § 211.57.

XI

(Bonding)

With respect to crystalline cefadroxil monohydrate imported prior to January 10, 1990, the conduct prohibited by paragraph III of this Order may be continued during the period in which this order is in effect subject to Respondent posting a bond in the amount of sixty-eight (68) percent of the entered value of crystalline cefadroxil monohydrate capsules or bulk powder in question. This bond provision does not apply to conduct which is otherwise permitted by paragraph IV of this Order. Crystalline cefadroxil

monohydrate capsules or bulk powder imported on or after January 10, 1990, are subject to the entry bond as set forth in the limited temporary exclusion order issued by the Commission on January 10, 1990, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders (53 Fed. Reg. 49133-34 (Dec. 6, 1988)).

The bond and any accompanying documentation is to be provided to and approved by the Commission prior to the commencement of conduct which is otherwise prohibited by paragraph III of this Order.

The bond is to be forfeited in the event that the President approves, or does not disapprove within the Presidential review period, the Commission's Orders of January 10, 1990, or any subsequent final order issued after the completion of Investigation No. 337-TA-293, unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or unless Respondent exports the products subject to this bond or destroys them and provides certification to that effect satisfactory to the Commission.

The bond is to be released in the event the President disapproves this Order and no subsequent order is issued by the Commission and approved, or not disapproved, by the President, upon service on Respondent of an Order issued by the Commission based upon application therefor made by Respondent to the Commission.

By Order of the Commission.

Kenneth R. Mason

Secretary

Issued: January 10, 1990

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN CRYSTALLINE CEFADROXIL MONOHYDRATE	)	Investigation No. 337-TA-293

ORDER TO CEASE AND DESIST

IT IS HEREBY ORDERED THAT Purepac Pharmaceutical Co., 200 Elmora Avenue, Elizabeth, New Jersey 07207, cease and desist from marketing, distributing, offering for sale, selling, or otherwise transferring in the United States certain imported crystalline cefadroxil monohydrate during the pendency of USITC Investigation No. 337-TA-293.

I

(Definitions)

As used in this Order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainant" shall mean Bristol-Myers Squibb Company, New York, N.Y.

(C) "Respondent" shall mean Purepac Pharmaceutical Co., 200 Elmora Avenue, Elizabeth, New Jersey 07207.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than the above Respondent or its majority owned and/or controlled subsidiaries, their successors, or assigns.

(E) "United States" shall mean the fifty states, the District of Columbia, and Puerto Rico.

II

(Applicability)

The provisions of this Order shall apply to Respondent and to its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and/or majority owned business entities, successors, and assigns.

III

(Conduct Prohibited)

Respondent shall not market, distribute, offer for sale, sell, or otherwise transfer in the United States imported crystalline cefadroxil monohydrate that infringes claim 1 of U.S. Letters Patent 4,504,657, except under license of the patent owner.

IV

(Conduct Permitted)

Notwithstanding any other provisions of this Order, specific conduct otherwise prohibited by the terms of this Order, shall be permitted if, in a written instrument, such specific conduct is licensed or authorized by Complainant or related to the importation or sale of crystalline cefadroxil monohydrate thereof by or for the United States.

V

(Reporting)

For purposes of this reporting requirement, the reporting period shall cover the period from the date of this Order to March 16, 1990. This reporting requirement shall continue in force until the day after the Commission issues its final determination in Investigation No. 337-TA-293, unless, pursuant to subsection (j)(3) of section 337 of the Tariff Act of 1930, the President notifies the Commission within 60 days after the date he receives this Order, that he disapproves this Order.

Any failure to report shall constitute a violation of this Order.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission the following:

(A) Its sales or other transfers in the United States, measured in capsules of crystalline cefadroxil monohydrate, and in grams of bulk powder of crystalline cefadroxil monohydrate, for the period ending on March 16, 1990; and

(B) All contracts, whether written or oral, entered into during the period ending on March 16, 1990, to sell or otherwise transfer capsules or bulk powder of crystalline cefadroxil monohydrate.

In connection with the sales or other transfers referred to in paragraphs (A) and (B) above, Respondent shall provide the Commission with two copies of all invoices, delivery orders, bills of lading, and other documents concerning the importation or sale in question. Such copies shall be attached to the reports required by paragraphs (A) and (B) above.

VI

(Compliance and Inspection)

(A) For the purposes of securing compliance with this Order, Respondent shall retain any and all records relating to the sale in the United States of crystalline cefadroxil monohydrate referred to in paragraphs (V)(A) and (V)(B) above made and received in the usual and ordinary course of its business, whether in detail or in summary form, for a period of two (2) years from the close of the fiscal year to which they pertain.

(B) For the purpose of determining or securing compliance with this Order and for no other purpose, and subject to any privilege recognized by Federal Courts of the United States, Respondent shall furnish or otherwise make available for inspection and copying to duly authorized representatives of the Commission, and in the presence of counsel or other representative if Respondent so chooses, upon reasonable written notice by the Commission or its staff, all books, ledgers, accounts, correspondence, memoranda, financial reports, and other records or documents in its possession or control for the purpose of verifying any matter or statement contained in the reports required under section V of this Order.

VII

(Service of Cease and Desist Order)

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the date of issuance of this Order, a copy of the Order upon each of its respective officers, directors, managing agents, agents and employees who have any responsibility for the

marketing, distribution, or sale of imported crystalline cefadroxil monohydrate in the United States.

(B) Serve, within fifteen (15) days after the succession of any of the persons referred to in paragraph VII(A), a copy of this Order upon each successor.

(C) Maintain such records as will show the name, title, and address of each person described in paragraph VII(A) and (B) above upon whom this Order has been served, together with the date on which service was made.

(D) The obligations set forth in paragraphs VII (B) and (C) above shall remain in effect until the day after the Commission issues its final determination in Investigation No. 337-TA-293, unless, pursuant to subsection (j)(3) of section 337 of the Tariff Act of 1930, the President notifies the Commission within 60 days after the date he receives this Order, that he disapproves this Order.

VIII

(Confidentiality)

Information obtained by the means provided for in sections V and VI of this Order will be made available only to the Commission and its authorized representatives, will be entitled to confidential treatment, and will not be divulged by any authorized representative of the Commission to any person other than duly authorized representatives of the Commission, except as may be required in the course of securing compliance with this Order, or as otherwise required by law. Disclosure hereunder will not be made by the Commission without ten (10) days prior notice in writing to Respondent.

IX

(Enforcement)

Violation of this Order may result in any of the actions specified in section 211.56 of the Commission's Interim Rules of Practice and Procedure, 19 C.F.R. § 211.56, including an action for civil penalties in accordance with section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), and such other action as the Commission may deem appropriate. In determining whether Respondent is in violation of this Order, the Commission may infer facts adverse to Respondent if Respondent fails to provide adequate or timely information as required by this Order.

X

(Modification)

This Order may be modified by the Commission on its own motion or upon motion by any person pursuant to section 211.57 of the Commission's Interim Rules of Practice and Procedure, 19 C.F.R. § 211.57.

XI

(Bonding)

With respect to crystalline cefadroxil monohydrate imported prior to January 10, 1990, the conduct prohibited by paragraph III of this Order may be continued during the period in which this order is in effect subject to Respondent posting a bond in the amount of sixty-eight (68) percent of the entered value of crystalline cefadroxil monohydrate capsules or bulk powder in question. This bond provision does not apply to conduct which is otherwise permitted by paragraph IV of this Order. Crystalline cefadroxil

monohydrate capsules or bulk powder imported on or after January 10, 1990, are subject to the entry bond as set forth in the limited temporary exclusion order issued by the Commission on January 10, 1990, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders (53 Fed. Reg. 49133-34 (Dec. 6, 1988)).

The bond and any accompanying documentation is to be provided to and approved by the Commission prior to the commencement of conduct which is otherwise prohibited by paragraph III of this Order.

The bond is to be forfeited in the event that the President approves, or does not disapprove within the Presidential review period, the Commission's Orders of January 10, 1990, or any subsequent final order issued after the completion of Investigation No. 337-TA-293, unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or unless Respondent exports the products subject to this bond or destroys them and provides certification to that effect satisfactory to the Commission.

The bond is to be released in the event the President disapproves this Order and no subsequent order is issued by the Commission and approved, or not disapproved, by the President, upon service on Respondent of an Order issued by the Commission based upon application therefor made by Respondent to the Commission.

By Order of the Commission.

Kenneth R. Mason

Secretary

Issued: January 10, 1990

CERTAIN CRYSTALLINE
CEFADROXIL MONOHYDRATE

337-TA-293

CERTIFICATE OF SERVICE

I, Kenneth R. Mason hereby certify that the attached NOTICE OF ISSUANCE OF A TEMPORARY LIMITED EXCLUSION ORDER AND TEMPORARY CEASE AND DESIST ORDERS AND AMENDMENT OF THE NOTICE OF INVESTIGATION was served upon George Summerfield and upon the following parties via first class mail, and air mail where necessary on January 10, 1990.

Kenneth R. Mason, Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

For Complainant Bristol-Myers Company

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Edward W. Greason
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For Respondent Gema, S.A.

John D. Foley
Richard C. Komson
MORGAN & FINNEGAN
345 Park Avenue
New York, N.Y. 10154

For Respondents: Kalipharma, Inc., Purepac, Inc., Institute Biochimique, S.A. and Istituto Biochimico Italiano Industria Giovanni Lorenzini

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CERTAIN CRYSTALLINE
CEFADROXIL MONOHYDRATE

337-TA-293

CERTIFICATE OF SERVICE Pg.2

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PUBLIC DISCLOSURE VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN CRYSTALLINE CEFADROXIL MONOHYDRATE	)	Investigation No. 337-TA-293 Temporary Relief Proceeding

COMMISSION OPINION 1/

I. BACKGROUND

On February 1, 1989, Bristol-Myers Company ("Bristol-Myers") (since renamed Bristol-Myers Squibb Company) filed a complaint and a motion for temporary relief with the Commission alleging violations of section 337 of the Tariff Act of 1930 2/ in the importation and sale of certain crystalline cefadroxil monohydrate. The complaint alleged infringement of claim 1 of U.S. Letters Patent 4,504,657 owned by Bristol-Myers.

Pursuant to Commission interim rule 210.24(e)(8), the Commission provisionally accepted Bristol-Myers's motion for temporary relief at the Commission meeting on March 8, 1989. The Commission also instituted an investigation into the allegations of Bristol-Myers's complaint and published a notice of investigation in the Federal Register. 3/ The notice named the following respondents: (1) Biocraft Laboratories, Inc. of Elmwood Park, N.J.; (2) Gema, S.A. of Barcelona, Spain; (3) Kalipharma, Inc. of Elizabeth, N.J.; (4) Purepac Pharmaceutical Co. of Elizabeth, N.J.;

1/ Chairman Brunsdale and Vice Chairman Cass dissent in a separate opinion from the Commission's determination to issue temporary cease and desist orders. They do not join section II.B. of this opinion.

2/ 19 U.S.C. § 1337.

3/ 54 Fed. Reg. 10740 (March 15, 1989).

(5) Istituto Biochimico Italiano Industria Giovanni Lorenzini S.p.A. of Milan, Italy ("IBI"); and (6) Institut Biochimique, S.A. of Massagno, Switzerland ("IBSA").

On May 13, 1989, the presiding administrative law judge ("ALJ") issued an initial determination ("ID") denying Bristol-Myers's motion for temporary relief. On June 13, 1989, the Commission issued a determination not modifying or vacating the ID insofar as it denied that motion. Bristol-Myers appealed the Commission's denial to the United States Court of Appeals for the Federal Circuit. On December 8, 1989, the Federal Circuit issued a decision reversing the Commission's determination. 4/ The Federal Circuit determined that Bristol-Myers had established that there is reason to believe that there is a violation of section 337 in the importation, sale for importation, or sale in the United States of the pertinent crystalline cefadroxil monohydrate, and that the public interest supports issuance of temporary relief. The Federal Circuit's decision effectively directed the Commission to grant temporary relief to Bristol-Myers.

After issuance of the Federal Circuit's decision, the Commission solicited and received from the parties comments on the issues of temporary relief and bonding not resolved by the decision. On January 10, 1990, the Commission issued an order granting temporary relief to Bristol-Myers.

This opinion explains the Commission's basis for its determinations: (1) to issue a temporary limited exclusion order; (2) to issue temporary cease and desist orders against the domestic respondents; (3) not to make

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4/ Bristol-Myers Co. v. USITC, App. No. 89-1530 (Fed. Cir. Dec. 8, 1989). The Federal Circuit's mandate issued on December 29, 1989.

temporary relief subject to posting of a bond by complainant; and (4) to establish respondents' bond in the amount of 68 percent of the entered value of the imported articles.

II. FORM OF TEMPORARY RELIEF

A. Scope of the Temporary Exclusion Order

Bristol-Myers requested that the Commission issue a temporary exclusion order (TEO) of general application. Commission precedent establishes that a complainant seeking a general exclusion order must prove "both a widespread pattern of unauthorized use of its patented invention and certain business conditions from which one might reasonably infer that foreign manufacturers other than the respondents to the investigation may attempt to enter the U.S. market with infringing articles." 5/

The only probative evidence on the issue of "widespread pattern of unauthorized use" is that four foreign entities manufacture the cefadroxil currently being imported into the United States. 6/ 7/ That is not a strong

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5/ Certain Airless Spray Pumps and Components Thereof, Inv. No. 337-TA-90, USITC Pub. 1199 at 18 (May 1981).

6/ Three are respondents: Gema, IBI, and IBSA. The fourth, Dobfar Industria Chimica Farmaceuticia S.p.A. of Milan, Italy, is not a respondent. Bristol-Myers did not allege the existence of additional foreign pharmaceutical manufacturers that could export infringing product to the United States.

7/ Vice Chairman Cass regards the number of importing firms as not having independent significance to the propriety of a general exclusion order. Rather, he believes that this evidence is at best a source of inferences regarding the ease of entry into the markets for arguably infringing imports. Direct evidence on that point, discussed infra, amply demonstrates the absence of a basis for issuance of a general temporary exclusion order in this investigation.

showing. In cases in which the Commission issues general exclusion orders, typically the number of existing foreign manufacturers is much larger. 8/

There is no evidence in the record demonstrating the existence of business conditions that would make new foreign entrants into the market likely. Bristol-Myers did not submit any evidence indicating that new foreign manufacturers could easily enter the U.S. market or that existing foreign pharmaceutical manufacturing facilities could be inexpensively adapted for cefadroxil manufacture. To the contrary, the record indicates that Bristol-Myers itself has made a substantial investment in cefadroxil manufacturing facilities and equipment. 9/ There appears to be at least one significant barrier to entry for any new foreign manufacturer's product, viz., the necessity that such product receive approval from the Food and Drug Administration before it can be marketed in the United States.

Because Bristol-Myers's showing concerning a "widespread pattern of unauthorized use" is marginal and that concerning "business conditions" is practically non-existent, we cannot conclude that it has demonstrated that

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8/ See Certain Strip Lights, Inv. No. 337-TA-287 (seven foreign factories produced infringing goods in addition to the one owned by named respondent); Certain Reclosable Plastic Bags and Tubing, Inv. No. 337-TA-266, USITC Pub. 2171 (March 1989) (infringement by 10 foreign respondent manufacturers and at least one foreign non-respondent manufacturer). In one case, however, a general exclusion order was issued although the existence of only three foreign manufacturers was established. See Certain Apparatus for Installing Electrical Lines, Inv. No. 337-TA-196, USITC Pub. 1858 (May 1986). In Electrical Lines, in contrast to the current record in this investigation, there was a strong showing of business conditions that would make new foreign entrants into the market likely: "[v]irtually any machine shop having a drill grinder and induction welding equipment can produce the product." Id. at 14.

9/ The ID on temporary relief found that Bristol-Myers had invested $20 million in the plant and equipment it uses to produce cefadroxil.

issuance of a TEO of general scope is warranted. Accordingly, we have issued a limited TEO. 10/

10/ Commissioner Newquist notes that while he is satisfied that the Spray Pumps criteria for issuance of a general exclusion order have not been met, a serious question remains whether, in the event the Commission issues a final determination of a violation of section 337, the issuance of a limited exclusion order against only the three named foreign respondents would provide adequate relief. Documents in the record (including copies of pleadings filed in a federal district court action brought by Bristol-Myers) indicate that two domestic non-respondents, Zenith Laboratories, Inc., and Interchem Corporation, have imported (or at least intend to import) certain crystalline cefadroxil monohydrate produced by an Italian manufacturer, Dobfar Industria Chimica Farmaceuticia S.p.A. According to Bristol-Myers, those imports are covered by the '657 patent. See Bristol-Myers Comments at 24, Exs. A and B; Letter from Arnold H. Krumholz, Counsel for Zenith (December 22, 1989). Zenith's representatives contend that the importation of crystalline cefadroxil monohydrate imported from Dobfar does not infringe the '657 patent because that patent is invalid. Of course the Commission's preliminary determination of patent invalidity has been reversed by the Federal Circuit.

Foreign producers of accused imports should have an opportunity to participate in the Commission's investigations. Indeed, the Commission has recently stated that evidence of unauthorized importation by numerous foreign producers was included among the factors supporting the issuance of a general exclusion order, so that complainants would be encouraged to name as respondents any and all firms that they reasonably believe are acting in violation of section 337. See Certain Chemiluminescent Compositions, Inv. No. 337-TA-285, Commission Opinion on Remedy at 10 (Aug. 17, 1989). In this case, however, the importation of certain crystalline cefadroxil monohydrate manufactured by Dobfar commenced only after issuance of the ID that the '657 patent was likely to be invalid. See Bristol-Myers Comments at 24 n.10. Thus, Dobfar was not named as a respondent. While it appears that, traditionally, the only forms of exclusion orders issued by the Commission are limited exclusion orders against named respondents or general exclusion orders, Commissioner Newquist is concerned that, if (in any final relief phase) the Commission were again to find that Bristol-Myers has not made a case for the issuance of a general exclusion order, we would fail to award effective relief -- i.e., relief that prevents the importation or distribution of infringing crystalline cefadroxil monohydrate by a limited number of non-respondents. Accordingly, if the Commission requests briefing on remedy in connection with the permanent relief phase of this investigation, he would invite all interested parties (including the various non-respondents) to address the appropriateness of issuing a limited exclusion order or cease and desist order against a non-respondent.

B. Issuance of Cease and Desist Orders

Bristol-Myers and the Commission investigative attorney ("IA") requested that the Commission issue temporary cease and desist orders. Respondents opposed this request.

Section 337 expressly gives the Commission the authority to issue temporary cease and desist orders in addition to any temporary exclusion order. 11/ Traditionally, the Commission has issued cease and desist orders when it has determined that a substantial volume of imports in respondents' domestic inventory is a potential cause of substantial injury to the domestic industry. 12/ On the other hand, requests for cease and desist orders have been denied when there is no evidence of import stockpiling. 13/

The lack of any information in the record concerning the current inventory levels of respondents makes it impossible to determine authoritatively whether they are currently stockpiling. 14/ Even when the record does not contain reliable information concerning inventory levels, however, issuance of cease and desist orders may still be appropriate when circumstances suggest the existence of significant inventories.

11/ 19 U.S.C. § 1337(f)(1).

12/ See Certain Compound Action Metal Cutting Snips, Inv. No. 337-TA-197, USITC Pub. No. 1831 at 4 (March 1986).

13/ See Certain Heavy-Duty Staple Gun Tackers, Inv. No. 337-TA-137, USITC Pub. 1506 at 5 (March 1984).

14/ The ID on temporary relief contains findings concerning the amount of product in the domestic respondents' inventories as of March 1989, the month that respondents began importing and marketing generic cefadroxil in the United States.

The procedural history of this litigation has provided a strong incentive for the domestic respondents to increase their inventories. Once the Federal Circuit issued its opinion, respondents knew that Bristol-Myers was virtually certain to receive some sort of temporary relief from the Commission. 15/ The Federal Circuit, however, could not order such relief itself; moreover, the Commission could not order temporary relief until it received the Federal Circuit's mandate, which was not issued until 21 days after its decision. The time lapse between release of the Federal Circuit decision and issuance of any Commission TEO provided the domestic respondents with a "window" in which they had one final opportunity to augment their inventories by importing without posting a bond. We have concluded that this provides an adequate basis for issuance of temporary cease and desist orders against the domestic respondents. 16/ 17/

15/ Biocraft admitted as much to the press: "The company, a generic drug maker, said that it appears likely that Bristol-Myers Squibb Co. will be able to secure an injunction blocking imports of a particular form of cefadroxil, an antibiotic." Wall St. J., Dec. 12, 1989, at C9, col. 1.

Moreover, even before the Federal Circuit decision was issued, respondents surely knew of the risk that the Commission's TEO determination could be reversed by the Court and that the Commission would be required to grant Bristol-Myers's request for temporary relief. Consequently, we do not believe that respondents' arguments that imposition of a cease and desist order would be unfair because they have imported in "good faith" warrant extended comment.

16/ The Commission's long-standing practice has been to issue cease and desist orders only to domestic companies. See Certain Molded-In Sandwich Panel Inserts, Inv. No. 337-TA-99, USITC Pub. No. 1246 at 23 (May 1982). We are not aware of any circumstances in this investigation warranting deviation from this practice.

17/ Commissioners Rohr and Newquist note that the filing of an appeal from the Commission's denial of temporary relief, and the prospect of a possible reversal of the Commission's determination, also may have created an incentive for domestic respondents to augment their inventories.

We emphasize that our determination to issue temporary cease and desist orders on the basis of the current record which does not contain conclusive information about current inventory levels has been motivated by the unusual procedural history of the temporary relief proceedings outlined above and the need for expeditious action in light of the Federal Circuit decision. Because similar special circumstances are unlikely to be present when we consider whether to issue permanent cease and desist orders in this investigation, assuming arguendo that such an inquiry is necessary, we are likely then to require more specific information about respondents' inventory levels before issuing such orders.

III. COMPLAINANT'S BOND

Section 337 provides that, when a complainant has been granted temporary relief, "[t]he Commission may require the complainant to post a bond as a prerequisite to issuance of a [temporary relief] order under this subsection." 18/ The Commission's interim regulations state that "[t]he Commission's policy is to require the posting of bond in every case." 19/ 20/ The regulations further state that the bond is likely to be in an amount ranging from 10 to 100 percent of the complainant's annual

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18/ 19 U.S.C. § 1337(e)(2).

19/ 19 C.F.R. § 210.24(e)(1)(iii).

20/ Vice Chairman Cass notes his concerns over this bonding rule. First, this bonding rule may be insufficiently structured to notify complainants of the bond likely to be required in any given case. See Certain Concealed Cabinet Hinges and Mounting Plates, Inv. No. 337-TA-289 (Concurring and Dissenting Views of Vice Chairman Ronald A. Cass). Second, the bond may be based on an inappropriate measure, the complainant's sales revenue, given the focus of the temporary exclusion order on imports into the United States and the purpose of the bond to deter frivolous motions for exclusion of such imports.

sales revenues and licensing royalties (if any) from the domestic product at issue. 21/

A complainant, however, may persuade the Commission that a bond should not be required. 22/ Factors that the Commission will consider in determining whether to impose a bond include the strength of the complainant's case, burden on complainant, whether respondents have filed responses to the request for temporary relief, burden on respondents, and any other relevant legal, equitable, or public interest considerations. 23/

Bristol-Myers has met its burden of establishing that imposition of a complainant's bond would be inappropriate. The policy behind the bonding requirement is to deter complainants from filing frivolous motions for temporary relief or using temporary relief proceedings as a means of harassing respondents. In light of the Federal Circuit decision, Bristol-Myers's request can hardly be deemed frivolous or improper.

This is a highly unusual case in which the Commission's section 337 court of review has rendered a ruling dictating that temporary relief must be granted before the complainant has actually received such relief. In light of that ruling, the Commission need not safeguard against the possibility that such relief has been requested or granted improperly. The policy considerations that make imposition of complainant's bond appropriate in the usual case, where it is the Commission that has made the initial determination to grant temporary relief, are absent here.

21/ 19 C.F.R. § 210.24(e)(1)(iv).

22/ See 19 C.F.R. § 210.24(e)(1)(iii).

23/ Id.

Accordingly, we have concluded that Bristol-Myers should not be required to post bond as a condition of receiving temporary relief.

IV. RESPONDENTS' BOND

The Commission's interim rules indicate that respondents' bond is to be set at an amount "that would offset any competitive advantage resulting from the alleged unfair methods of competition and unfair acts enjoyed by persons benefitting from the importation of the articles in question." 24/ Contrary to respondents' assertions, the record indicates that their importation of cefadroxil provides them with a competitive advantage, viz., respondents are able to offer cefadroxil at a lower price because they, unlike Bristol-Myers, have not incurred research and development costs. 25/ Accordingly, imposition of some bond on respondents is appropriate.

We have concluded that the bond should be computed on the basis of the difference between respondents' and Bristol-Myers's prices for cefadroxil monohydrate. 26/ The Commission has used such a computation method in prior

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24/ See 19 C.F.R. § 210.58(a)(3).

25/ It is for this reason that the ID on temporary relief concluded that Bristol-Myers had demonstrated that immediate and substantial harm to the domestic industry was likely to occur. Material submitted by Bristol-Myers confirms the accuracy of this projection; it shows that the firm's cefadroxil sales for the period April through November 1989 were 42 percent less than sales for the same period in 1988. See Bristol-Myers Comments, Declaration of Bruce R. Ross, Ex. A.

26/ Vice Chairman Cass recognizes that this means of setting respondent's bond is in line with Commission practice, and that in temporary relief proceedings the parties do not have a great deal of time in which to compile evidence that would bear on the degree of competitive advantage gained by infringing the patent rights at issue. However, he believes that price differences are likely to reflect many things, only one of which might be differential investments in research and development. In future cases he would ask that parties more critically address the appropriate measure of respondents' bond and offer evidence to assist the Commission on

(continued...)

proceedings. 27/ Moreover, no party has suggested a workable alternative.

The ID on temporary relief found that Bristol-Myers' selling prices were 68 percent higher than those of respondents. 28/ No party indicated in its comments that this price differential has changed appreciably. We have therefore established respondents' bond at 68 percent of entered value for both cefadroxil capsules and bulk cefadroxil. 29/ We do not agree with the IA or respondents that this bond should be reduced because of the public interest in having cefadroxil available for purchase in the United States at prices lower than those charged by Bristol-Myers. The Federal Circuit's decision precludes the Commission from concluding in this case that any

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26/(...continued)
setting the bond.

27/ See Certain High Intensity Retroreflective Sheeting, Inv. No. 337-TA-268, USITC Pub. 2121 at 12 (September 1988); Certain Foam Earplugs, Inv. No. 337-TA-184, USITC Pub. 1671 at 4 (March 1985).

28/ Respondents were found to charge about for a 100-capsule bottle of cefadroxil, while Bristol-Myers charged for the same quantity.

29/ Because the record indicates that Bristol-Myers neither purchases nor sells bulk cefadroxil in arm's-length transactions, there is no basis for an actual price or cost comparison for the bulk product between Bristol-Myers and respondents. It could be assumed that if Bristol-Myers did sell bulk product, it would maintain the same bulk product/capsule price ratio as do respondents. Because, in that event, the percentage price differential between Bristol-Myers and respondents for bulk product would be the same as that for capsules, the same bond for both products is appropriate.

public interest in lower prices can prevail over Bristol-Myers's interest in protection from allegedly unfair acts. 30/ 31/

30/ See Bristol-Myers v. USITC, slip op. at 15.

31/ Vice Chairman Cass does not read the Federal Circuit opinion in precisely this way. Rather, he understands the court to have held that, in this case, the public's interest in the protection of Bristol-Myers's patent rights outweighed their interest in access to lower-priced cefadroxil, resulting in a balance of the four factors traditionally considered by the Commission in favor of issuing temporary relief. This does not preclude the Commission in the future from determining that the public interest weighs against a grant of temporary relief in balancing these four factors, or from considering price levels in the context of the public interest.

In the matter of:	)	
CERTAIN CRYSTALLINE CEFADROXIL MONOHYDRATE	)	Investigation No. 337-TA-293

DISSENTING VIEWS OF CHAIRMAN BRUNSDALE AND VICE CHAIRMAN CASS ON THE ISSUANCE OF TEMPORARY CEASE AND DESIST ORDERS

We concur with the Commission's grant of temporary relief in this investigation as directed by the United States Court of Appeals for the Federal Circuit in its mandate dated December 29, 1989. Further, we concur with the Commission's actions with respect to complainant's and respondents' bonds.[1] We believe, however, that relief should consist solely of the issuance of a limited temporary exclusion order and that, for the reasons discussed below, issuance of cease and desist orders is not appropriate under the circumstances of this case.

Cease and desist orders prohibit the sale in the United States of imported goods that have already entered the U.S. customs territory, while exclusion orders serve in varying degrees to prohibit the entry of the infringing goods into this country. If granted as temporary relief, and during the presidential review period of a final determination, both cease and desist and exclusion orders may allow the prohibited act to continue under

[1] As noted in footnote 26 of the Commission Opinion, Vice Chairman Cass is not satisfied that the difference in price between complainant's and respondents' product is a good measure of the competitive advantage gained by infringing the '657 patent. Upon issuance of the Federal Circuit's opinion in this case, the Commission specifically requested that the parties provide the Commission with evidence in addition to the evidence compiled in the initial temporary relief proceeding regarding the appropriate respondents' bond. Neither party, however, responded with information useful to the Commission beyond verification of the price differential.

bond. These orders provide distinct forms of relief and the Commission in the past always has evaluated them separately under different standards.

As noted in the Commission Opinion, the Commission has traditionally issued cease and desist orders based on evidence that respondents have built inventories of the infringing product sufficient to injure the domestic industry substantially even after importation of the products is prohibited.[2] The Commission has stated that its rationale "for issuing both an exclusion order and a cease and desist order [is] to provide complete relief to complainant" when the respondent domestic importers have significant inventories of infringing imports, the continued sales of which would further injure complainant.[3] Thus the Commission has issued cease and desist orders when necessary to ensure that the relief provided by an exclusion order is not undermined by sales of infringing imports out of uncharacteristically large inventories built by domestic importers during the pendency of the proceeding.[4]

The Omnibus Trade and Competitiveness Act of 1988 made clear that the Commission is authorized to issue cease and desist orders in addition to, rather than only in lieu of, exclusion orders and eliminated the requirement

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[2] See Certain High Intensity Retroreflective Sheeting, Inv. No. 337-TA-268, USITC Pub. 2121 at 9 (September 1988) ("Retroreflective Sheeting"); Certain Compound Action Metal Cutting Snips and Components Thereof, Inv. No. 337-TA-197, USITC Pub. 1831 at 9 (March 1986)("Metal Cutting Snips").

[3] Retroreflective Sheeting at 9.

[4] See Metal Cutting Snips at 9 ("The facts of this investigation compel the Commission to issue both a general exclusion order and cease and desist orders if effective relief is to be afforded complainant. As we have noted, there have been importations of large numbers of infringing metal cutting snips, which have yet to be sold. These inventories are a potential cause of substantial injury to the domestic industry. The failure to prohibit further sale of these inventories would effectively deny remedy for this potential injury.")

that the Commission consider injury to the domestic industry with respect to patents and certain other forms of intellectual property in determining whether relief is warranted.[5] However, Congress' changes to the statute neither prohibit the Commission from continuing to employ its traditional test for the issuance of cease and desist orders nor direct the Commission to adopt new standards. Congress merely made clear that the Commission has the power to do something that we had already concluded we could do,[6] i.e., issue cease and desist orders in conjunction with exclusion orders in the appropriate circumstances.[7] As indicated in the legislative history, Congress specifically contemplated that circumstances meriting the issuance of cease and desist orders could be evidence of "stockpiling during the pendency of an investigation."[8] Although Congress did not state that this is the only circumstance in which a cease and desist order would be appropriate, nothing

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[5] Pub. L. 100-418, 102 Stat. 1107, § 1342(a)(1) & (4)(A), codified at 19 U.S.C. § 1337(a) & (f)(1).

[6] See Retroreflective Sheeting at 9 ("In recent Commission decisions, a majority of the Commission has concluded that section 337 permits issuance of both an exclusion order an a cease and desist order, even when there is only one unfair act being remedied.")

[7] See S. Rep. No. 71, 100th Cong., 1st Sess. 131 (1987); H. Rep. No. 40, 100th Cong., 1st Sess. 159 (1987). Both reports contain the following statement regarding the proposed changes to the statutory provisions governing the Commission's issuance of cease and desist orders:

> The Commission has interpreted the current language as prohibiting it from issuing both an exclusion order and a cease and desist order to remedy the same unfair act. There are circumstances, however, where it is in the public interest to issue both. For example, a cease and desist order prohibiting a domestic respondent from selling the imported infringing product in the United States may be appropriate when the product has been stockpiled during the pendency of an investigation and an exclusion order may be appropriate to prevent future shipments of the infringing product.(emphasis added).

[8] Id.

in the language of the statute or the legislative history indicates that Congress expected the Commission to relax its traditional standard after passage of the 1988 Act.

Having recognized that cease and desist orders are appropriate only when the domestic industry requires protection from infringing imports beyond that afforded by an exclusion order, the Commission should not now begin issuing cease and desist orders whenever complainant so requests, even in the absence of record evidence that respondents have built inventories substantially in excess of normal levels that threaten significant harm to the domestic industry. In a proceeding such as this, a temporary exclusion order imposing a bond on importation of the subject products should sufficiently protect the complainant during the pendency of the investigation from competition by imports that have benefited from infringement to the extent that the bond accurately compensates for the changes in the price of the import due to the infringement. The Commission should reserve issuance of cease and desist orders for cases in which something more than exclusion is required to protect complainant adequately. Complainant would need such protection only if respondents had amassed substantial inventories.

In this case the record is devoid of evidence regarding the current level of respondents' inventories. The ALJ collected evidence regarding inventories during the original TEO proceedings in the spring of 1989, as the ALJ may do under the Commission's interim rule 210.24(e), but this information is no longer germane; it does not shed light on the inventories that now exist and the change in inventories during the course of the proceeding. The record compiled in the investigation on permanent relief does not contain this information because the ALJ is prohibited under Commission interim rule

210.58(b) from taking evidence or hearing arguments with respect to remedy.[9] Although the parties may submit such information to the Commission during our consideration of the appropriate permanent relief and bonds, the Commission is not yet at that stage of the permanent relief proceeding.

The majority argues that the Commission may base the issuance of the temporary cease and desist orders on a finding that the circumstances of the case would likely lead to a rapid build-up of inventories of the subject cefadroxil by importers in the United States. They then conclude essentially that stockpiling the infringing imports in anticipation of sanctions under Section 337 would have been the reasonable course of action for respondents to have taken, without any basis in the record whatsoever for this conclusion.

Such assumptions are inherently unreliable. In light of the widely differing inventory systems maintained by different industries and the differing conditions of importation for different products, the Commission can not simply assume, as it has in this case, that inventories are at a particular level or that importers are able to significantly increase their stock of imported products during a particular time period in response to Commission action.

Moreover, the circumstances of this case can just as easily be interpreted in a manner opposite to that of the majority. The ID on the TEO motion finding a reasonable indication that the '657 patent was invalid was adopted by the Commission without comment. Although Bristol-Myers filed an

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[9] We have noted before that the Commission is often handicapped by this rule and we have suggested that it be revised. See Certain Strip Lights, Inv. No. 337-TA-287 (Separate Views of Chairman Brunsdale and Vice Chairman Cass). Clearly the Commission would benefit from findings by the ALJ on the facts that the Commission must examine in considering the public interest and determining the appropriate remedy and bonds.

appeal, given the legal standard on review of such matters,[10] there was no reason for respondent to anticipate reversal. Furthermore, as time passed, respondent would reasonably have continued normal business operations as the deadline for the issuance of the final ID drew nearer without the issuance of the Federal Circuit's decision.[11] Even the three-week window between release of the Federal Circuit's decision and the issuance of its mandate would scarcely seem sufficient time to arrange for a large shipment of cefadroxil.

As recently urged in another investigation, the Commission does not have unbounded discretion to impose remedies based on its evaluation of the circumstances relating to a case.[12] By the same token, speculation by the Commission about the circumstances that may have motivated respondents in this instance cannot form a reasonable basis for the issuance of cease and desist orders, or any other remedy, in this case. The knowledge that the Commission may choose to draw inferences from circumstances outside the record of the case hardly provides the parties with adequate guidance as to the strictures of the law.

In sum, there is nothing on the record to suggest that this case warrants issuance of cease and desist orders under the Commission's traditional test with its specific requirement of a large build-up of import

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[10] The appellate court applies the same standard to the review of Commission determinations as it applies to review of district court actions: whether the Commission abused its discretion, committed an error of law, or seriously misjudged the evidence. See H.H Robertson, Co. v. United Steel Deck, Inc., 820 F.2d 384, 387, 2 USPQ2d 1926, 1927 (Fed. Cir. 1987)

[11] The Federal Circuit issued its mandate on December 29, 1989. The final ID was due on January 18, 1990. Had the Federal Circuit not issued its decision before the Commission's final decision, the TEO matter would have been moot.

[12] See Certain Concealed Cabinet Hinges and Mounting Plates, Inv. No. 337-TA-289 (Concurring and Dissenting Views of Vice Chairman Ronald A. Cass).

inventories. We therefore dissent from the grant of this remedy.