

Complaint

120 F.T.C.

IN THE MATTER OF

HOECHST AG

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT

Docket C-3629. Complaint, Dec. 5, 1995--Decision, Dec. 5, 1995

This consent order settles alleged violations of federal law prohibiting unfair or deceptive acts and practices and unfair methods of competition arising from the \$7.1 billion merger of Hoechst AG and Marion Merrell Dow Inc. The consent order, among other things, requires Hoechst -- a pharmaceutical firm -- to provide Biovail Corporation International with a letter of access to the toxicology data necessary to secure additional FDA approvals for a hypertension and cardiac drug called Tiazac (diltiazem). It also requires Hoechst to return any confidential information obtained from Biovail; to refrain from using the information; to dismiss a patent infringement lawsuit filed by Marion Merrell Dow regarding Tiazac; to withdraw a citizen petition Marion Merrell Dow filed with the Food and Drug Administration relating to Tiazac; and to agree not to file any subsequent litigation against Biovail regarding diltiazem. In addition, the consent order requires Hoechst to divest the rights to either Trental or Beraprost (two drugs intended to treat intermittent claudication, a painful leg cramping condition); to divest the rights to Pentasa (or the generic formulation), which is one of two oral forms of mesalamine used to treat ulcerative colitis and Crohn's Disease; and to divest the rights to Rifadin (or the generic formulation), which is used to treat tuberculosis. The required divestitures have to be made to Commission-approved entities, within nine months of the date of the order.

Appearances

For the Commission: *Laura A. Wilkinson, Elizabeth A. Jex, David L. Inglefield and Pamela L. Taylor.*

For the respondent: *William C. Pelster, Skadden, Arps, Slate, Meagher & Flom and Bruce H. Kublik, Covington & Burling, Washington, D.C.*

COMPLAINT

The Federal Trade Commission ("Commission"), having reason to believe that respondent Hoechst AG ("Hoechst"), a German corporation subject to the jurisdiction of the Commission, has acquired all of the voting securities of Marion Merrell Dow Inc.

("MMD"), a Delaware corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, ("FTC Act"), 15 U.S.C. 45; and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

I. RESPONDENT

1. Respondent Hoechst is a corporation organized, existing, and doing business under and by virtue of the laws of Germany with its principal executive offices located in Frankfurt am Main, Germany. Respondent Hoechst operates in the United States through its wholly-owned subsidiaries, Hoechst Corporation and Hoechst-Roussel Pharmaceuticals, Inc., with their principal executive offices located at Route 202-206, Somerville, New Jersey. Respondent Hoechst is the majority owner of Copley Pharmaceuticals, Inc., a corporation, with its principal executive offices located in Canton, Massachusetts.

2. MMD is a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its principal place of business located at 9300 Ward Parkway, Kansas City, Missouri.

II. JURISDICTION

3. Respondent Hoechst is, and at all times relevant herein has been, engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. 12, and is a corporation whose business affects commerce as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. 44.

III. THE MERGER

4. Respondent Hoechst has acquired all of the voting securities of MMD for consideration valued at approximately \$7.1 billion ("Merger"). The combined entity is doing business in the United States as Hoechst Marion Roussel, Inc.

IV. THE RELEVANT MARKETS

5. The relevant lines of commerce in which to analyze the effects of the Merger are the research, development, manufacture and sale of:

- (1) Once-a-day diltiazem, which is used to treat hypertension (high blood pressure) and angina (severe chest pains);
- (2) Oral dosage forms of mesalamine, which is used to treat the gastrointestinal diseases of ulcerative colitis and Crohn's Disease;
- (3) Rifampin, which is used to treat tuberculosis (TB); and
- (4) Drugs approved by the Food and Drug Administration ("FDA") for the treatment of intermittent claudication, a severe cramping in the legs caused by inadequate blood flow to the affected muscles due to arteriosclerosis.

6. For purposes of this complaint, the United States is the relevant geographic area in which to analyze the effects of the Merger.

V. STRUCTURE OF THE MARKETS

7. The once-a-day diltiazem market is highly concentrated as measured by the Herfindahl-Hirschmann Index. MMD's Cardizem CD[®] has a dominant share of the once-a-day diltiazem market. Sales of once-a-day diltiazem products in the U.S. amounted to approximately \$1 billion in 1994. Prior to the Merger, Hoechst and Biovail International Corporation ("Biovail") were jointly developing a new once-a-day diltiazem product, Tiazac[®], that would have competed against MMD's Cardizem CD[®].

8. Hoechst devised a plan to "fix-it-first" whereby it returned to Biovail its rights to Tiazac[®] prior to the Merger. The purported fix fails to remedy the anticompetitive effects of the Merger, because it leaves Biovail as a less effective competitor than it would have been absent the Merger.

9. The market for oral dosage forms of mesalamine is highly concentrated as measured by the Herfindahl-Hirschmann Index. MMD's Pentasa[®] has a significant share of the market for oral dosage forms of mesalamine. There is only one other oral dosage form of mesalamine approved by the FDA. Sales of mesalamine amounted to approximately \$70 million in 1994. Prior to the Merger, Hoechst

begun research and development of a generic oral dosage form of mesalamine that would have competed against MMD's Pentasa®.

10. The rifampin market is highly concentrated as measured by the Herfindahl-Hirschmann Index. MMD's Rifadin® has a dominant share of the rifampin market. Sales of rifampin amounted to approximately \$18 million in 1994. Prior to the Merger, Hoechst was one of only a few companies that had begun research and development of a generic rifampin product that would have competed against MMD's Rifadin®.

11. The market for drugs to treat intermittent claudication is highly concentrated as measured by the Herfindahl-Hirschmann Index. Hoechst's Trental® is the only drug approved by the FDA for the treatment of intermittent claudication, and Hoechst is developing improved formulations of Trental®. In 1994, Trental®'s sales were approximately \$180 million. MMD is one of only a few companies engaged in advanced stages of research and development of drugs for use in the treatment of intermittent claudication that would have competed against Hoechst's Trental® franchise.

VI. BARRIERS TO ENTRY

12. Entry into the relevant markets is difficult and time consuming. FDA regulations create long lead times for the introduction of new drugs. Additionally, patents create large and often insurmountable barriers to entry.

VII. EFFECTS OF THE MERGER

13. The effects of the Merger may be substantially to lessen competition or tend to create a monopoly in the once-a-day diltiazem market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. 45. In 1993, Hoechst and MMD began the negotiations that ultimately resulted in the Merger. At the same time, Hoechst and Biovail were developing Tiazac®, a once-a-day diltiazem product. The pendency of the merger negotiations affected Hoechst's incentives with respect to the development of Tiazac®.

14. Just before finalizing the Merger, Hoechst returned its rights to Tiazac® to Biovail. The purported "fix-it-first" failed to remedy the anticompetitive effects of the Merger, because it leaves Tiazac®

as a less effective competitive product than it would have been absent the Merger.

15. The Merger eliminates actual and perceived potential competition between MMD's Cardizem[®] CD and Tiazac[®]. Effective competition between Tiazac[®] and Cardizem[®] CD will benefit consumers by leading to lower prices for once-a-day diltiazem.

16. The Merger provides the leading competitor in the once-a-day diltiazem market with access to competitively sensitive non-public information relating to Tiazac[®], thereby: (1) reducing innovation in the market for once-a-day diltiazem; and (2) increasing prices in the market for once-a-day diltiazem.

17. The Merger also enhances the likelihood of collusion or interdependent coordination between or among the firms in the market for once-a-day diltiazem.

18. The effects of the Merger may be substantially to lessen competition or tend to create a monopoly in the market for oral dosage forms of mesalamine in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. 45. The Merger (1) eliminates actual potential competition in the market for oral dosage forms of mesalamine and (2) enhances the likelihood of collusion or interdependent coordination between or among the firms in the market for oral dosage forms of mesalamine.

19. The effects of the Merger may be substantially to lessen competition or tend to create a monopoly in the market for rifampin in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. 45. The Merger eliminates actual potential competition in the market for rifampin.

20. The effects of the Merger may be substantially to lessen competition or tend to create a monopoly in the market for drugs for the treatment of intermittent claudication in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. 45. The Merger eliminates actual potential competition in the market for drugs for the treatment of intermittent claudication.

VIII. VIOLATIONS CHARGED

21. The Merger described in paragraph four constitutes a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. 45.

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of the merger of Hoechst AG ("Hoechst"), through its United States subsidiary, Hoechst Corporation, and Marion Merrell Dow Inc. ("MMD"), and Hoechst, hereinafter sometimes referred to as "respondent," having been furnished thereafter with a copy of a draft of the complaint that the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that respondent has violated the said Acts, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, and having duly considered the comments filed thereafter by interested persons pursuant to Section 2.34 of its Rules, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Hoechst is a corporation organized, existing, and doing business under and by virtue of the laws of Germany, with its principal place of business located at 65926 Frankfurt am Main, Germany.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

I.

It is ordered, That, as used in this order, the following definitions shall apply:

A. "*Respondent*" or "*Hoechst*" means Hoechst AG, its directors, officers, employees, agents and representatives, successors and assigns; its subsidiaries, divisions, groups and affiliates controlled by Hoechst AG; subsidiaries, divisions, groups and affiliates in which Hoechst AG owns more than 25 percent of the voting securities; and the respective directors, officers, employees, agents and representatives, and the respective successors and assigns of each.

B. "*MMD*" means Marion Merrell Dow Inc., its directors, officers, employees, agents and representatives, successors and assigns; its subsidiaries, divisions, groups and affiliates controlled by Marion Merrell Dow Inc.; and the respective directors, officers, employees, agents and representatives, and the respective successors and assigns of each.

C. "*Merger*" means the merger of Hoechst and MMD through the acquisition by Hoechst of the voting securities of MMD pursuant to a Stock Purchase Agreement and an Agreement and Plan of Merger both dated as of May 3, 1995.

D. "*Commission*" means the United States Federal Trade Commission.

E. "*FDA*" means the United States Food and Drug Administration.

F. "*NDA*" means new drug application.

G. "*ANDA*" means abbreviated new drug application.

H. "*Diltiazem*" means any formulation of the compound diltiazem hydrochloride used in the treatment of hypertension or angina.

I. "*Biovail*" means Biovail Corporation International, organized and existing under the laws of Canada and with its offices and principal place of business at 460 Comstock Road, Scarborough, Ontario, Canada, including its successors, licensees and assigns.

J. "*Biovail diltiazem products*" means the sustained release and/or extended release diltiazem products that Hoechst was developing with Biovail pursuant to the Rights Agreement that Hoechst and Biovail entered into on June 30, 1993.

K. "*Documents*" means all computer files and written, recorded, and graphic materials of every kind. The term "documents" includes electronic correspondence and drafts of documents, originals and all copies of documents, and copies of documents the originals of which are not in the possession, custody or control of the company.

L. "*Non-public information*" means any information or documents not in the public domain furnished by Biovail to Hoechst in connection with the Biovail diltiazem products. Non-public information shall not include information that subsequently becomes public or falls within the public domain through no violation of this order by respondent or nor shall it include information that subsequently becomes known to respondent from a third-party not in breach of a confidential disclosure agreement.

M. "*Beraprost*" means the prostaglandin analog(s) licensed by Toray Industries, Inc. to MMD used for the treatment of peripheral arterial disease, including, but not limited to, intermittent claudication.

N. "*Beraprost assets*" means all of MMD's U.S. assets and rights relating to the research and development, manufacture and sale of Beraprost, that are not part of MMD's physical facilities. "Beraprost assets" include, but are not limited to, all rights to brand or trade name, formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, distribution information, customer lists, information stored on management information systems (and specifications sufficient for the acquirer to use such information), software specific to MMD's Beraprost, inventory sufficient for the acquirer to complete all safety and efficacy studies, clinical trials or bioequivalency studies necessary to obtain FDA approvals, and all data, contractual rights, materials and information relating to

obtaining FDA approvals and other government or regulatory approvals for the United States.

O. "*Trental*[®]" means the compound pentoxifylline marketed by Hoechst for use in the treatment of vascular disease, including, but not limited to, intermittent claudication.

P. "*Trental*[®] assets" means all of Hoechst's U.S. assets and rights relating to the research and development, manufacture and sale of *Trental*[®], including the unique physical assets used by Hoechst to manufacture *Trental*[®] and all of its brand names and trade names. "*Trental*[®] assets" include, but are not limited to, all rights to brand or trade name, formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, distribution information, customer lists, information stored on management information systems (and specifications sufficient for the acquirer to use such information), software specific to Hoechst's *Trental*[®], and all data, contractual rights, materials and information relating to obtaining FDA approvals and other government or regulatory approvals for the United States.

Q. "*Mesalamine*" means the compound mesalamine used for the treatment of ulcerative colitis and Crohn's disease.

R. "*Mesalamine assets*" means either (1) all of Hoechst's U.S. assets and rights relating to the research and development, manufacture and sale of mesalamine by Hoechst that are not part of Hoechst's physical facilities and that were not acquired through the Merger; or (2) all of MMD's U.S. assets and rights relating to the research and development, manufacture and sale of mesalamine by MMD, including the unique physical assets used MMD to manufacture mesalamine and all of its brand names and trade names. "*Mesalamine assets*" include, but are not limited to, all rights to brand or trade names, all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, distribution information, information stored on management information systems (and specifications sufficient for the acquirer to use such information), inventory sufficient for the acquirer to complete all ongoing safety and efficacy studies, clinical trials or bioequivalency studies necessary to obtain FDA approvals and all data, contractual

rights, materials and information relating to obtaining FDA approvals and other government or regulatory approvals for the United States.

S. "*Rifampin*" means the compound rifampin used for the treatment of tuberculosis.

T. "*Rifampin assets*" means either (1) all of Hoechst's U.S. assets and rights relating to the research and development, manufacture and sale of rifampin by Hoechst that are not part of Hoechst's physical facilities and that were not acquired through the Merger; or (2) MMD's U.S. assets and rights relating to the research and development, manufacture and sale of rifampin by MMD, including the unique physical assets used by MMD to manufacture rifampin and all of its brand names and trade names. "*Rifampin assets*" include, but are not limited to, all rights to brand or trade names, all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, distribution information, information stored on management information systems (and specifications sufficient for the acquirer to use such information), inventory sufficient for the acquirer to complete all ongoing safety and efficacy studies, clinical trials or bioequivalency studies necessary to obtain FDA approvals and all data, contractual rights, materials and information relating to obtaining FDA approvals and other government or regulatory approvals for the United States.

U. "*Acquirer*" means the entity or entities to whom Hoechst shall divest the assets required to be divested pursuant to this order.

V. "*Contract manufacture*" means the manufacture of Trental®, mesalamine or rifampin, as applicable, by Hoechst for sale to an acquirer in a form acceptable for commercial sale in the United States, in each form of packaging used by respondent or MMD in the distribution and sale of such product, with information including, but not limited to, the name and identification codes of the acquirer inscribed on the packaging, and packaged in units specified by the acquirer, as permitted by the FDA.

W. "*Cost*" means respondent's or MMD's actual per unit cost of manufacturing the assets to be divested pursuant to this order.

X. "*Formulation*" means any and all information, including patent, trade secret information, technical assistance and advice, relating to the manufacture of the assets to be divested pursuant to this order that meet FDA approved specifications therefor.

II.

It is further ordered, That:

A. Within seven (7) days of the date this order becomes final:

1. Respondent shall grant to Biovail the right of reference to the pharmacology, toxicology and animal reproductive toxicology data contained in MMD's NDA No. 18-602 for diltiazem on file with the FDA. Respondent shall make the necessary filings with the FDA authorizing the FDA to refer to the appropriate section(s) of MMD's NDA No. 18-602 for such data (including, but not limited to, pharmacology and toxicology data) in support of Biovail's NDA No. 20-401 for the Biovail diltiazem products, including any supplemental NDAs or related NDAs. Provided however, the right of reference granted to Biovail pursuant to this paragraph does not constitute a general release of the data contained in MMD's NDA No. 18-602, except as it might appear in labelling.

2. Respondent shall withdraw the Citizen Petition(s) that MMD filed with the FDA relating to NDAs under Section 505(b)(2) of the Food, Drug and Cosmetics Act, 21 U.S.C. 355(b)(2), including the NDA for the Biovail diltiazem products. Respondent shall not file any further Citizen Petition with the FDA relating to the NDA under Section 505(b)(2) of the Food, Drug and Cosmetics Act, 21 U.S.C. 355(b)(2), that could have the effect of delaying the approval of the NDA for the Biovail diltiazem products.

3. Respondent shall file a stipulation of dismissal with prejudice to MMD of all litigation currently pending in the United States between or among MMD, Hoechst, and Biovail, including, but not limited to, *Marion Merrell Dow Inc., Carderm Capital L.P. and Elan plc v. Hoechst-Roussel Pharmaceuticals, Inc.*, No. 93-5074 (D.N.J), and shall not institute or cause any other person to institute any patent infringement action against Biovail relating to the Biovail diltiazem products.

4. Respondent shall return to Biovail all documents relating to the research, development, FDA approval, patenting, manufacture, marketing, or sale of the Biovail diltiazem products.

B. Respondent shall not use any non-public information relating to the Biovail diltiazem products and shall not provide, disclose or

otherwise make available to MMD any non-public information relating to the Biovail diltiazem products.

C. The purpose of this paragraph II is to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.

III.

It is further ordered, That:

A. Respondent shall divest, absolutely and in good faith, within nine (9) months of the date this order becomes final, either the Beraprost assets or Trental® assets.

B. Respondent shall divest the Beraprost assets or Trental® assets only to an acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission. The purpose of the divestiture of the Beraprost assets or Trental® assets is to ensure continued competition between Trental® and Beraprost, in the same manner in which Trental® and Beraprost would compete absent the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.

C. The time period for divestiture pursuant to this paragraph III of this order shall be tolled if and when respondent:

1. Provides to the Commission objective evidence, including, but not limited to, results of clinical trials, indicating that, based on a compound's medical profile, and through no fault of respondent, the Beraprost assets are not viable or marketable; and

2. Petitions the Commission to modify this order, pursuant to Section 5(b) of the FTC Act and Section 2.51 of the Commission's Rules of Practice, based on the circumstances described in paragraph III.C.1 of this order.

This tolling of the time period for divestiture shall end when the Commission rules on respondent's petition to modify this order.

IV.

It is further ordered, That:

A. Respondent shall divest, absolutely and in good faith, within nine (9) months of the date this order becomes final, the Mesalamine assets.

B. Respondent shall divest the Mesalamine assets only to an Acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission. The purpose of the divestiture of the Mesalamine assets is to ensure continued competition between Hoechst's mesalamine and MMD's mesalamine, in the same manner in which these compounds would compete absent the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.

V.

It is further ordered, That:

A. Respondent shall divest, absolutely and in good faith, within nine (9) months of the date this order becomes final, the Rifampin assets.

B. Respondent shall divest the Rifampin assets only to an acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission. The purpose of the divestiture of the Rifampin assets is to ensure continued competition between Hoechst's rifampin and MMD's rifampin, in the same manner in which these compounds would compete absent the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.

VI.

It is further ordered, That:

A. Upon reasonable notice and request from the acquirer(s), to Hoechst, Hoechst shall provide information, technical assistance and advice to the acquirer(s) with respect to any assets divested pursuant to this order such that the acquirer(s) will be capable of continuing all applicable research, development and manufacturing. Such assistance shall include reasonable consultation with knowledgeable employees

of Hoechst and training at the acquirer's facility for a period of time sufficient to satisfy the acquirer's management that its personnel are adequately knowledgeable about the assets divested pursuant to this order. However, respondent shall not be required to continue providing such assistance for more than twelve (12) months after divestiture of such assets. Respondent may require reimbursement from the acquirer(s) for all of its own direct costs incurred in providing the services required by this subparagraph. Direct costs, as used in this subparagraph, means all actual costs incurred exclusive of overhead costs. If an acquirer hires any of respondent's officers, directors, agents, or employees whose work relates to a divested asset being acquired by the acquirer, respondent shall waive any confidentiality or non-competition employment rights relating to assets divested pursuant to this order that respondent has against such employee.

B. Pending divestiture of the assets to be divested pursuant to this order, respondent shall:

1. Take such actions as are necessary to prevent the destruction, removal, wasting, deterioration or impairment of the assets to be divested pursuant to this order, except for ordinary wear and tear; and
2. Maintain research and development of the assets required to be divested by this order, at the levels planned by either Hoechst or MMD for such assets as of June 1, 1995.

C. Hoechst shall maintain the physical assets, if any exist, necessary to manufacture Trental®, Beraprost, mesalamine and rifampin, until respondent's obligations pursuant to paragraphs III, IV, V, VI and VII of this order have been fulfilled. The maintenance of physical assets described in this subparagraph shall not exceed two (2) years following divestitures pursuant to paragraphs III, IV and V of this order.

D. Respondent shall obtain from each acquirer a certification of the acquirer's good faith intention to obtain in an expeditious manner all necessary FDA approvals to manufacture and sell in the United States the assets to be divested pursuant to this order and a commitment by the acquirer to use reasonable diligence to continue to research and develop the assets to be divested pursuant to this order for sale in the United States.

VII.

It is further ordered, That:

A. If respondent fulfills its obligations pursuant to this order by divesting assets relating to a product for which the FDA has issued either approval of a NDA or an ANDA (hereinafter Divested Product), respondent shall execute an agreement (hereinafter Divestiture Agreement) with the acquirer of such Divested Product.

B. Each Divestiture Agreement shall include the following and respondent shall commit to satisfy the following:

1. Respondent shall contract manufacture and deliver to the acquirer in a timely manner the requirements of the acquirer for the Divested Product at respondent's or MMD's cost for a period not to exceed five (5) years from the date the Divestiture Agreement is approved, or six (6) months after the date the acquirer obtains all necessary FDA approvals to manufacture the Divested Product for sale in the United States, whichever is earlier.

2. Respondent shall commence delivery of the Divested Product to the acquirer within two (2) months from the date the Commission approves the acquirer and the Divestiture Agreement.

3. After respondent commences delivery of the Divested Product to the acquirer pursuant to paragraph VII.B.2 of this order, all inventory of the Divested Product produced by respondent for the U.S. market at the facility that produced such Divested Product, regardless of the date of its production, may be sold by respondent only to the acquirer.

4. Respondent shall make representations and warranties to the acquirer that the Divested Product contract manufactured by respondent for the acquirer meets the FDA approved specifications therefor and is not adulterated or misbranded within the meaning of the Food, Drug and Cosmetic Act, 21 U.S.C. 321, *et seq.* Respondent shall agree to indemnify, defend and hold the acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Divested Product contract manufactured by respondent to meet FDA specifications. This obligation shall be contingent upon the acquirer giving respondent prompt, adequate notice of such claim, cooperating fully in the defense of such claim, and permitting respondent to assume the

sole control of all phases of the defense and/or settlement of such claim, including the selection of counsel. This obligation shall not require respondent to be liable for any negligent act or omission of the acquirer or for any representations and warranties, express or implied, made by the acquirer that exceed the representations and warranties made by respondent to the acquirer.

5. During the term of contract manufacturing, upon reasonable request by the acquirer, respondent shall make available to the trustee appointed pursuant to paragraph VIII.A. of this order all records kept in the normal course of business that relate to the cost of manufacturing the Divested Product.

VIII.

It is further ordered, That:

A. Within forty-five (45) days of the date this order becomes final, the Commission shall appoint a trustee to ensure that respondent expeditiously performs its responsibilities required by this order. Respondent shall consent to the following terms and conditions regarding the trustee's powers, duties, authorities, and responsibilities under this paragraph:

1. The Commission shall select the trustee, subject to the consent of respondent, which consent shall not be unreasonably withheld. If respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after notice by the staff of the Commission to respondent of the identity of any proposed trustee, respondent shall be deemed to have consented to the selection of the proposed trustee.

2. Within ten (10) days after the appointment of the trustee, respondent shall execute a trust agreement that, subject to the prior approval of the Commission, confers on the trustee all the rights and powers necessary to permit the trustee to assure respondent's compliance with the terms of this order, including the rights and powers necessary to divest assets, if the trustee is so directed by the Commission. As part of the trustee agreement, the trustee shall execute confidentiality agreements with respondent.

3. The trustee shall serve until either (a) the acquirer(s) has filed a complete application with the FDA for approval to manufacture and

sell a product(s) based on the Trental[®] assets or the Beraprost assets, the Rifampin assets and the Mesalamine assets, as applicable; (b) the trustee determines that the acquirer(s) has abandoned its efforts to obtain FDA approval to manufacture and sell a product(s) based upon the Trental[®] assets or the Beraprost assets, the Rifampin assets and the Mesalamine assets, as applicable; or (c) the trustee determines that the acquirer(s) has failed to exercise reasonable diligence in research and development toward obtaining FDA approval to manufacture and sell a product(s) based upon the Trental[®] assets or the Beraprost assets, the Rifampin assets and the Mesalamine assets, as applicable, which lack of diligence will have been certified to and accepted by the Commission, whichever comes first. The trustee's service shall continue for no more than two (2) years following divestiture of the Trental[®] assets or the Beraprost assets, the Rifampin assets and the Mesalamine assets, as applicable.

4. The trustee shall have full and complete access to the personnel, books, records, facilities and technical information related to the Trental[®] assets or the Beraprost assets, the Rifampin assets and the Mesalamine assets, or to any other relevant information, as the trustee may reasonably request, including, but not limited to, all records kept in the normal course of business that relate to the research and development of and the cost of manufacturing Trental[®] or Beraprost, mesalamine and rifampin. Respondent shall develop such financial or other information as the trustee may request and shall cooperate with the trustee. Respondent shall take no action to interfere with or impede the trustee's accomplishment of his or her responsibilities pursuant to this order.

5. The trustee shall serve, without bond or other security, at the cost and expense of respondent, on such reasonable and customary terms and conditions as the Commission may set. The trustee shall have authority to employ, at the cost and expense of respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all expenses incurred. The Commission shall approve the account of the trustee, including fees for his or her services.

6. Respondent shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other expenses

incurred in connection with the preparations for, or defense of, any claim whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

7. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in paragraph VIII.A. of this order.

8. The Commission may on its own initiative or at the request of the trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the requirements of this order.

9. The trustee shall report in writing to respondent and the Commission every one hundred and eighty (180) days concerning the trustee's obligations pursuant to this paragraph VIII.

B. Respondent shall comply with all reasonable directives of the trustee regarding respondent's obligations to comply with this order.

C. The trustee may require respondent to manufacture Beraprost for use by the acquirer in conducting clinical trials or other actions as required by the FDA if:

1. The acquirer has depleted its inventory of Beraprost acquired pursuant to the divestiture;

2. The acquirer has a need to conduct further trials or studies prior to submission of an application to the FDA to manufacture and sell a product based on the Beraprost assets; and

3. Despite good faith efforts to establish its own manufacturing capability for Beraprost, the acquirer has not succeeded in doing so as of the time Beraprost is needed for such clinical trials or other actions as required by the FDA.

The trustee shall determine reasonable compensation for respondent, based upon the costs of manufacture for such production.

IX.

It is further ordered, That:

A. If respondent has not divested, absolutely and in good faith and with the Commission's prior approval, (1) either the Trental®

assets or the Beraprost assets; (2) the Mesalamine assets; and (3) the Rifampin assets, within the time required by paragraphs III.A., IV.A., and V.A. of this order, the Commission may direct the trustee appointed pursuant to paragraph VIII of this order to accomplish any divestiture required pursuant to this order. Neither the decision of the Commission to direct the trustee nor the decision of the Commission not to direct the trustee to divest the assets required to be divested shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to Section 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the respondent to comply with this order. Respondent shall consent to the following terms and conditions regarding the trustee's powers, duties, authorities, and responsibilities under this paragraph.

B. If the trustee is directed under subparagraph A. of this paragraph to divest any assets, respondent shall consent to the following terms and conditions regarding the trustee's powers, duties, authority, and responsibilities:

1. The Commission shall extend the authority and responsibilities of the trustee appointed under paragraph VIII of this order to include divesting any assets required to be divested by this order that have not been divested.

2. Subject to the prior approval of the Commission, the trustee shall have the exclusive power and authority to divest any assets required to be divested pursuant to this order that have not been divested.

3. Within ten (10) days after the extension of the trustee's authority and responsibilities, respondent shall amend the existing trust agreement in a manner that, subject to the prior approval of the Commission and, in the case of a court-appointed trustee, of the court, transfers to the trustee all rights and powers necessary to permit the trustee to effect the divestitures required by this order.

4. The trustee shall have twelve (12) months from the date the Commission approves the extension of the trustee's authorities and responsibilities as described in paragraph IX.B.3 to accomplish the divestiture(s), which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve month period, the trustee has submitted a plan of divestiture(s) or believes that

divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed trustee, by the court; provided, however, the Commission may extend this period only two (2) times.

5. The trustee shall have full and complete access to the personnel, books, records, facilities and technical information related to the assets to be divested by the trustee, or to any other relevant information, as the trustee may reasonably request, including, but not limited to, all records kept in the normal course of business that relate to the research and development of, and the cost of manufacturing, Trental®, Beraprost, mesalamine and rifampin. Respondent shall develop such financial or other information as the trustee may request and shall cooperate with the trustee. Respondent shall take no action to interfere with or impede the trustee's accomplishment of the divestiture. Any delays in divestiture caused by respondent shall extend the time for divestiture under this paragraph in an amount equal to the delay, as determined by the Commission or, for court-appointed trustee, by the court.

6. The trustee shall use his or her best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to respondent's absolute and unconditional obligation to divest at no minimum price; to assure that respondent enters into Divestiture Agreement(s) that comply with the provisions of paragraph VII; to assure that respondent and the acquirer(s) comply with the remaining provisions of this order. The divestitures and the Divestiture Agreement(s) shall be made in the manner set forth in paragraphs III, IV, V, VI and VII of this order; provided, however, that if the trustee receives *bona fide* offers from more than one acquiring entity for any of the assets to be divested pursuant to this order, and if the Commission determines to approve more than one such acquiring entity for any of the assets to be divested pursuant to this order, the trustee shall divest to the acquiring entity selected by respondent from among those approved by the Commission.

7. The trustee shall serve, without bond or other security, at the cost and expense of respondent, on such reasonable and customary terms and conditions as the Commission may set. The trustee shall have authority to employ, at the cost and expense of respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the trustee's duties

and responsibilities. The trustee shall account for all monies derived from the sale and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for his or her services, all remaining monies shall be paid at the direction of the respondent. The trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the trustee's divesting the assets to be divested.

8. Respondent shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparations for, or defense of, any claim whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

9. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in paragraph VIII.A. of this order.

10. The Commission or, in the case of a court-appointed trustee, the court may on its own initiative or at the request of the trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestitures required by this order.

11. The trustee shall report in writing to respondent and the Commission every sixty (60) days concerning the trustee's efforts to accomplish the divestiture(s) required by this order.

12. If a divestiture application filed pursuant to paragraph III.A. is pending before the Commission, and respondent petitions the Commission to modify this order based on the conditions in paragraph III.C., then the Commission shall not approve the divestiture application until it rules on the petition to modify.

X.

It is further ordered, That, for the purpose of determining or securing compliance with this order, respondent shall permit any duly authorized representatives of the Commission:

A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of respondent, relating to any matters contained in this order; and

B. Upon five (5) days' notice to respondent, and without restraint or interference from respondent, to interview officers, directors, or employees of respondent, who may have counsel present regarding such matters.

XI.

It is further ordered, That, within sixty (60) days after the date this order becomes final and every sixty days (60) days thereafter until respondent has fully complied with the provisions of paragraphs II, III, IV, V, VI and VII of this order, respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this order. Respondent shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with paragraphs II, III, IV, V, VI and VII of this order, including a description of all substantive contacts or negotiations for accomplishing the divestiture and the identity all parties contacted. Respondent shall include in its compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning divestiture.

XII.

It is further ordered, That respondent shall notify the Commission at least thirty (30) days prior to any proposed change in respondent such as dissolution, assignment, sale resulting in the emergence of a successor, or the creation or dissolution of subsidiaries, or any other change that may affect compliance obligations arising out of this order.

Complaint

120 F.T.C.

IN THE MATTER OF

SANTA CLARA COUNTY MOTOR CAR DEALERS ASSOCIATION

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3630. Complaint, Dec. 13, 1995--Decision, Dec. 13, 1995*

This consent order prohibits, among other things, a California association from carrying out, participating in, inducing or assisting any boycott or concerted refusal to deal with any newspaper, periodical, television or radio station, and requires the association to amend its by-laws to incorporate the stipulated prohibition, and to distribute the amended by-laws and the final Commission order to each of its members.

Appearances

For the Commission: *Ralph E. Stone and Pamela A. Gill.*

For the respondent: *Stephen V. Bomse, Heller, Ehram, White & McAuliffe, San Francisco, CA.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that the Santa Clara County Motor Car Dealers Association, an unincorporated association, hereinafter sometimes referred to as "the Association" or "respondent," has violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent Association is an unincorporated association organized, existing and doing business under and by virtue of the laws of the State of California, with its principal office and place of business at 336 East Hamilton Avenue, Campbell, California.

PAR. 2. The Association is a trade association representing the interests of new automobile and truck dealers in Santa Clara County,