IN THE MATTER OF

THE DOW CHEMICAL COMPANY, ET AL.

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-3533. Complaint, Sept. 23, 1994--Decision, Sept. 23, 1994

This consent order requires, among other things, Marion Merrell Dow Inc. to license its dicyclomine formulations and production technology to a third party within twelve months, and to contract manufacture dicyclomine for the third party while that party awaits Food and Drug Administration approval to sell its own dicyclomine. The consent order also prohibits, for ten years, acquisition of any dicyclomine manufacturing, production or distribution capabilities without prior Commission approval.

Appearances

For the Commission: *Ann B. Malester, Claudia R. Higgins, James Egan* and *Mary Lou Steptoe.*

For the respondents: *Michael Malina, Kaye, Scholer, Fierman, Hays & Handler*, New York, N.Y. *Edward H. Stratemeier*, in-house counsel for Marion Merrell Dow Inc., Kansas City, MO.

COMPLAINT

The Federal Trade Commission ("Commission"), having reason to believe that respondents, The Dow Chemical Company ("Dow"), a corporation subject to the jurisdiction of the Commission, and Marion Merrell Dow Inc. ("MMD"), a subsidiary of Dow and a corporation subject to the jurisdiction of the Commission, acquired certain stock of the Rugby-Darby Group Companies, Inc. ("Rugby"), a corporation also 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 by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 11 of the Clayton Act, as amended, 15 U.S.C. 21, and Section 5(b) of the FTC Act, as amended, 15 U.S.C. 45(b), stating its charges as follows:

I. DEFINITIONS

1. For the purposes of this complaint, the following definitions apply:

(a) "*Respondent Dow*" or "*Dow*" means The Dow Chemical Company, a corporation organized and doing business under the laws of the state of Delaware, its predecessors, subsidiaries, divisions, groups and affiliates controlled by Dow and their respective directors, officers, employees, agents and representatives acting on behalf of Dow, and their successors and assigns.

(b) "*Respondent MMD*" or "*MMD*" means Marion Merrell Dow Inc., a corporation organized and doing business under the laws of Delaware, its predecessors, subsidiaries, divisions, groups and affiliates controlled by MMD and their respective directors, officers, employees, agents and representatives acting on behalf of MMD, and their successors and assigns.

(c) "*Rugby*" means Rugby Group, Inc.

(d) "*Commission*" means the Federal Trade Commission.

(e) "*Acquisition*" means the acquisition by MMD of certain stock of Rugby relating to the production of generic pharmaceutical products, which stock is the subject of a stock purchase agreement dated October 4, 1993.

II. THE RESPONDENTS

2. Respondent Dow, which controls MMD and holds a majority of MMD's stock, is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business located at 2030 Dow Center, Midland, Michigan.

3. Respondent MMD, a subsidiary of Dow, is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business located at 9300 Ward Parkway, Kansas City, Missouri.

4. MMD manufactures and sells pharmaceutical products and products for hospital use, including cardiovascular products, respiratory products, smoking cessation products and gastrointestinal products, such as Bentyl® (the branded dicyclomine hydrochloride), an antispasmodic drug used for the treatment of functional or irritable bowel syndrome.

5. Respondents at all times relevant herein have been engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. 12, and are corporations whose business affects commerce as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. 44.

III. THE ACQUIRED COMPANY

6. Rugby is a corporation organized and existing under the laws of the state of New York, with its principal offices located at 100 Banks Avenue, Rockville Centre, New York.

7. Rugby manufactures and sells pharmaceutical products, including generic dicyclomine hydrochloride used for the treatment of irritable bowel syndrome.

8. Rugby 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.

IV. THE ACQUISITION

9. On October 4, 1993, MMD and Rugby signed a stock purchase agreement whereby MMD acquired certain stock of Rugby for approximately $300 million.

V. THE RELEVANT MARKET

10. The relevant line of commerce in which to analyze MMD's acquisition is the market for dicyclomine hydrochloride capsules and tablets.

11. The relevant section of the country is the United States.

12. The relevant market is highly concentrated. MMD and Rugby are the only United States Food and Drug Administration approved manufacturers of dicyclomine hydrochloride capsules and tablets.

VI. ENTRY CONDITIONS

13. Entry into the relevant market is difficult and time consuming.

VII. COMPETITION

14. Prior to the acquisition, MMD and Rugby were actual competitors in the relevant market.

VIII. EFFECTS OF THE ACQUISITION

15. The effect of the acquisition may be substantially to lessen competition or tend to create a monopoly in the relevant 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 the following ways, among others:

(a) The acquisition eliminated actual, direct and substantial competition between MMD and Rugby;
(b) The acquisition increased the likelihood that MMD will exercise market power in the relevant market; and
(c) The acquisition created a monopoly in the manufacture and sale of dicyclomine hydrochloride capsules and tablets.

IX. VIOLATIONS CHARGED

16. The acquisition described in paragraph nine 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 having initiated an investigation of the consummated acquisition of certain stock of Rugby-Darby Group Companies, Inc. ("Rugby") by Marion Merrell Dow Inc. ("MMD"), a subsidiary of The Dow Chemical Company ("Dow") (collectively referred to as "respondents"), and respondents having been furnished thereafter with a copy of a draft of complaint that the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge respondents 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

Respondents, their attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by respondents 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 respondents 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 the respondents have 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, now in further conformity with the procedure described 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 Dow is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its principal place of business located at 2030 Dow Center, Midland, Michigan.

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

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, 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. "*Dow*" means The Dow Chemical Company, its predecessors, subsidiaries, divisions, groups and affiliates controlled by Dow, and

its respective directors, officers, employees, agents and representatives, and their respective successors and assigns.

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

C. "*Rugby*" means Rugby Group, Inc., its predecessors, subsidiaries, divisions, groups and affiliates controlled by Rugby, and its respective directors, officers, employees, agents and representatives, and their respective successors and assigns.

D. "*Respondents*" means Dow and MMD.

E. "*Commission*" means the Federal Trade Commission.

F. "*Acquisition*" means the acquisition by respondents of certain Rugby stock that is the subject of a stock purchase agreement dated October 4, 1993.

G. "*Rugby intangible dicyclomine assets*" means those assets relating to the manufacture and sale of dicyclomine tablets and capsules acquired in the Acquisition that are not part of Rugby's physical facilities or other tangible assets, including but not limited to all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, quality control data, research materials, technical information, management information systems, software, the Drug Master file, and all information relating to United States Food and Drug Administration ("FDA") approvals.

H. "*Potential New Entrant*" means the person(s) for whom MMD shall contract manufacture, and to whom MMD shall sell, dicyclomine tablets and capsules and license the Rugby intangible dicyclomine assets. The Potential New Entrant must be a generic or a branded pharmaceutical manufacturer with manufacturing facilities approved by the FDA for the manufacture of generic or branded pharmaceutical products in the United States.

I. "*Dicyclomine tablets and capsules*" means pharmaceutically acceptable finished tablets and capsules consisting of either 10mg or 20mg of dicyclomine hydrochloride U.S.P. manufactured under an approved New Drug Application ("NDA") or an approved Abbreviated New Drug Application ("ANDA") for sale in the United States and that have received at least an AB rating by the FDA.

J. "*Contract manufacture*" means the manufacture of an unlimited volume of dicyclomine tablets and capsules by MMD for sale

to a Potential New Entrant in finished packaged form suitable for commercial sale in the United States.

K. "*Finished packaged form*" means packaged in all forms required by the Potential New Entrant so as to optimize sales and distribution of the product, including but not limited to inscribing the name and identification codes of the Potential New Entrant on the packaging of dicyclomine capsules or tablets, and packaging the dicyclomine tablets and capsules in units required by the Potential New Entrant, as permitted by Rugby's existing ANDA.

L. "*Formulation*" means any and all information, including both patent and trade secret information, technical assistance and advice, relating to the manufacture of dicyclomine tablets and capsules that meet United States Food and Drug Administration approved specifications therefore.

II.

It is further ordered, That:

A. Within twelve (12) months from the date this order becomes final, MMD shall enter into an agreement (hereinafter "agreement"), in good faith:

1. To license to the Potential New Entrant in perpetuity a non-exclusive right to the Rugby intangible dicyclomine assets at no minimum price; and

2. To contract manufacture and deliver in a timely manner the volume of dicyclomine tablets and capsules requested by the Potential New Entrant, at a price not to exceed 48% of the Average Wholesale Price of Rugby's dicyclomine tablets and capsules in effect as of July 2, 1993.

MMD shall enter into such agreement to license and contract manufacture only with a Potential New Entrant that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission and that is consistent with the purposes of this order. The purposes of this order are: (a) to provide the means for establishing an ongoing, viable enterprise to replace the competition in the dicyclomine tablet and capsule market alleged in the Commission's complaint to have been eliminated by the

Acquisition; and (b) to remedy the lessening of competition alleged in the Commission's complaint to have resulted from the Acquisition.

B. The agreement shall require the Potential New Entrant to submit to the Commission a certification attesting to the Potential New Entrant's good faith intention and actual plan to obtain FDA approval of its own NDA or ANDA for the manufacture and sale of dicyclomine tablets and capsules in an expedited manner. The agreement shall terminate in the event that the Potential New Entrant fails to sell or discontinues the sale of contract manufactured dicyclomine tablets and capsules prior to obtaining FDA approval, or abandons its efforts or fails to obtain FDA approval of its own NDA or ANDA for dicyclomine tablets and capsules within seven (7) years from the date the Commission approves the agreement.

C. The agreement shall require the Potential New Entrant to submit to the Commission a verified written report setting forth in detail its efforts to sell contract manufactured dicyclomine tablets and capsules and to obtain FDA approvals necessary for manufacturing its own dicyclomine tablets and capsules. The agreement shall require such report to be submitted one (1) year from the date the agreement becomes effective and annually thereafter until contract manufacturing ceases. The agreement shall also require the Potential New Entrant to report to the Commission at least thirty (30) days prior to its discontinuing the sale of contract manufactured dicyclomine tablets and capsules or abandoning its efforts to obtain FDA approvals necessary for manufacturing its own dicyclomine tablets and capsules.

D. MMD shall deliver dicyclomine tablets and capsules to the Potential New Entrant within two (2) months from the date the Commission approves the Potential New Entrant and the agreement. The Potential New Entrant shall have the right to continue to purchase dicyclomine tablets and capsules from MMD pursuant to the agreement until six (6) months after the date that the Potential New Entrant obtains FDA approval of its own NDA or ANDA for the manufacture and sale of dicyclomine tablets and capsules in the United States.

E. MMD shall make representations and warranties to the Potential New Entrant that the contract manufactured dicyclomine tablets and capsules meet the United States Food and Drug Administration approved specifications therefore and are not adulterated or misbranded within the meaning of the Food, Drug and Cosmetic Act,

21 U.S.C. 321, *et seq.* MMD shall agree to indemnify, defend and hold the Potential New Entrant harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the manufactured dicyclomine tablets and capsules to meet the specifications. This obligation shall be contingent upon the Potential New Entrant giving MMD prompt, adequate notice of such claim, cooperating fully in the defense of such claim, and permitting MMD 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 MMD to be liable for any negligent act or omission of the Potential New Entrant or for any representations and warranties, express or implied, made by the Potential New Entrant that exceed the representations and warranties made by MMD to the Potential New Entrant.

F. Upon reasonable notice from and at the option of the Potential New Entrant, MMD shall provide information, technical assistance and advice sufficient to assist the Potential New Entrant in obtaining FDA approval for the manufacture and sale of dicyclomine tablets and capsules. Such assistance shall include reasonable consultation with knowledgeable employees of MMD and training at the Potential New Entrant's facility for a period of time sufficient to satisfy the Potential New Entrant's management that its personnel are appropriately trained in the manufacture of dicyclomine tablets and capsules.

G. While the obligations imposed by paragraphs II.A, II.D or paragraph III of this order are in effect, respondents shall take such actions as are necessary to maintain the viability and marketability of the Rugby intangible dicyclomine assets and the tangible assets needed to contract manufacture and sell dicyclomine tablets and capsules and to prevent the destruction, removal, wasting, deterioration or impairment of any of the Rugby intangible and tangible assets relating to the manufacture of dicyclomine tablets and capsules except in the ordinary course of business and except for ordinary wear and tear that does not affect the viability and marketability of the Rugby intangible and tangible assets.

III.

It is further ordered, That:

A. MMD shall consent to the appointment of a trustee by the Commission to terminate MMD's prior agreement, if any, and to enter into a new agreement on behalf of MMD with a Potential New Entrant selected by the trustee if:

1. MMD has not entered into an agreement to contract manufacture dicyclomine tablets and capsules and to license the Rugby intangible dicyclomine assets to a Potential New Entrant within twelve (12) months as provided for in paragraph II of this order; or

2. The Potential New Entrant terminates the agreement to contract manufacture, fails to sell, or discontinues the sale of contract manufactured dicyclomine tablets and capsules in the United States prior to obtaining FDA approval of its own NDA or ANDA for the manufacture and sale of dicyclomine tablets and capsules; or

3. The Potential New Entrant abandons its efforts or fails to obtain FDA approval of its own NDA or ANDA for dicyclomine tablets and capsules within seven (7) years from the date the Commission approves the agreement.

In the event the Commission or the Attorney General brings an action against respondents to enforce this order pursuant to Section 5(1) of the Federal Trade Commission Act, 15 U.S.C. 45(1), or any other statute enforced by the Commission, MMD shall consent to the appointment of a trustee in such action. Neither the appointment of a trustee nor a decision not to appoint a trustee under this paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it for any failure by respondents to comply with this order.

B. If a trustee is appointed by the Commission or a court pursuant to paragraph III.A of this order, MMD shall consent to the following terms and conditions regarding the trustee's powers, duties, authorities, and responsibilities:

1. The Commission shall select the trustee, subject to the consent of MMD, which consent shall not be unreasonably withheld. The trustee shall be a person with experience and expertise in acqui-

sitions and divestitures. If MMD 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 MMD of the identity of any proposed trustee, MMD shall be deemed to have consented to the selection of the proposed trustee.

2. Subject to the prior approval of the Commission, the trustee shall have the exclusive power and authority to enter into an agreement as specified in paragraph II of this order.

3. Within ten (10) days after appointment of the trustee, MMD shall execute a trust agreement 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 enter into the agreement required by paragraph II of this order.

4. The trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in paragraph III.B.3 to terminate any prior agreement and to enter into the agreement specified in paragraph II of this order, which agreement shall be subject to the prior approval of the Commission. If, however, at the end of the twelve (12) month period the trustee has submitted a plan or believes that the agreement required by paragraph II of this order can be entered into within a reasonable time, the twelve (12) month 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 the twelve (12) month period only two (2) times and for no longer than twelve (12) months each time.

5. The trustee shall have full and complete access to the personnel, books, records, facilities and technical information related to the manufacture of dicyclomine tablets and capsules and to the Rugby intangible dicyclomine assets, or to any other relevant information, as the trustee may reasonably request. Respondents shall cooperate with any reasonable request of the trustee. Respondents shall take no action to interfere with or impede the trustee's ability to enter into the agreement required by paragraph II of this order. Any delays in entering into the agreement required by paragraph II of this order caused by respondents shall extend the time under paragraph III.B.4 for entering into the agreement required by paragraph II of this order in an amount equal to the delay, as determined by the Commission or, for the 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 MMD's absolute and unconditional obligation to enter into the agreement required by paragraph II of this order at no minimum price. The agreement shall be made in the manner and with a Potential New Entrant as set out in paragraph II of this order; provided, however, if the trustee receives bona fide offers from more than one Potential New Entrant, and if the Commission determines to approve more than one such Potential New Entrant, the trustee shall enter into an agreement as required by paragraph II of this order with the Potential New Entrant selected by MMD from among those approved by the Commission.

7. The trustee shall serve, without bond or other security, at the cost and expense of MMD, on such reasonable and customary terms and conditions as the Commission or a court may set. The trustee shall have authority to employ, at the cost and expense of MMD, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers 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 agreement required by paragraph II of this order 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 MMD and the trustee's power shall be terminated.

8. Respondents 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 the 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 III.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 enter into the agreement required by paragraph II of this order.

11. The trustee shall report in writing to MMD and to the Commission every sixty (60) days concerning the trustee's efforts to enter into the agreement required by paragraph II of this order.

IV.

It is further ordered, That for a period of ten (10) years from the date this order becomes final, respondents shall not acquire, without the prior approval of the Commission, directly or indirectly, through subsidiaries, partnerships, or otherwise:

(a) Any stock, share capital, equity, leasehold or other interest in any concern, corporate or non-corporate, presently engaged in, or within the two years preceding such acquisition engaged in, the manufacture, production, distribution or sale of dicyclomine tablets and capsules in the United States; or

(b) Any assets currently used for or previously used for (and still suitable for use for) the manufacture and production of dicyclomine tablets and capsules in the United States from any concern, corporate or noncorporate, presently engaged in, or within the two years preceding the acquisition engaged in the manufacture, production, distribution or sale of dicyclomine tablets and capsules in the United States.

Provided, however, that the obligations imposed by this paragraph shall not terminate while the obligations of paragraphs II or III are in effect.

V.

It is further ordered, That:

A. Within sixty (60) days after the date this order becomes final and every sixty (60) days thereafter until the Commission has approved a Potential New Entrant, MMD 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, or has complied

with paragraphs II and III of the order. MMD 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 and III of this order, including a description of all substantive contacts or negotiations for entering into the agreement required by this order, including the identity of all parties contacted. MMD 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 the agreement required by paragraph II of this order.

B. One (1) year from the date this order becomes final and annually for the next nine (9) years on the anniversary of the date this order becomes final, and at such other times as the Commission may require, respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with paragraphs II, III and IV of this order.

Provided, however, that the obligations imposed by this paragraph shall not terminate while the obligations of paragraphs II or III are in effect.

VI.

It is further ordered, That, for the purpose of determining or securing compliance with this order, and subject to any legally recognized privilege, upon written request and on reasonable notice to respondents, respondents 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 respondents, relating to any matters contained in this consent order; and

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