

Complaint

IN THE MATTER OF

HOECHST MARION ROUSSEL, INC., ET AL.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket 9293; File No. 9810368**Complaint, March 16, 2000--Decision, May 8, 2001*

This consent order settles an administrative complaint addressing an agreement among Respondent Hoechst Marion Roussel, Inc. (“HMR”), Respondent Carderm Capital, L.P., and Respondent Andrx Corporation concerning competition between Cardizem CD – a prescription drug manufactured and sold by HMR that is used to treat hypertension (high blood pressure) and angina pectoris (chest pain) – and a generic version developed by Andrx. The order, among other things, prohibits the respondents (except in certain licensing arrangements) from entering into agreements (1) in which the first company to file an Abbreviated New Drug Application agrees with the New Drug Application Holder not to relinquish its right to a 180-day exclusivity period (as interpreted by the courts at the time of the agreement), or (2) in which the Abbreviated New Drug Application First Filer agrees not to develop or market a generic drug product that is not the subject of a claim of patent infringement. The order also prohibits certain interim settlements of patent litigation by a respondent – involving payments to the generic company, and in which the generic company temporarily refrains from bringing its generic product to market – unless they are approved by the court, and the respondent gives notice to the Commission to allow it time to present its views to the court. In addition, the order requires the respondents to give the Commission written notice 30 days before entering into such agreements in other contexts.

Participants

For the Commission: *Markus H. Meier, Bradley S. Albert, Seth C. Silber, Daniel A. Kotchen, Robin Moore, Elizabeth R. Hilder, Suzanne Michel, Jon M. Steiger, Patricia Allen, David R. Pender, Richard A. Feinstein, Kenneth M. Davidson, Daniel P. Ducore, Elizabeth A. Schneirov, Leslie Farber, and Daniel P. O’Brien.*

For the Respondents: *James M. Spears and Michael Koon, Shook, Hardy & Bacon LLP, Peter O. Safir and Stacy L. Ehrlich,*

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Kleinfeld, Kaplan & Becker, and Louis M. Solomon, Solomon, Zauderer, Ellenhorn, Frischer & Sharp.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission (“Commission”), having reason to believe that respondents Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation have engaged in conduct, as described herein, that violates Section 5 of the Federal Trade Commission Act, as amended, 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:

The Respondents

1. Respondent Hoechst Marion Roussel, Inc. (“Hoechst MRI”) is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 10236 Marion Park Drive, Kansas City, Missouri. Hoechst MRI is, directly or indirectly, a wholly-owned subsidiary of Aventis, S.A., which is incorporated under the laws of the Republic of France with its office and principal place of business at 25 Quai Paul Doumier, 92408 Courbevoie Cedex, France. Hoechst MRI is engaged in the development, manufacture, distribution, and sale of pharmaceutical and health care products in the United States. Among other products, Hoechst MRI manufactures and sells Cardizem CD, a cardiovascular drug used to treat hypertension and angina.

2. At all relevant times herein, Hoechst MRI has been, and is now, a corporation as “corporation” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

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3. Respondent Carderm Capital L.P. (“Carderm”) is a Delaware limited partnership having its office and principal place of business at Richmond House, 12 Par-la-Ville Road, Hamilton, Bermuda. Carderm is directly or indirectly owned or controlled by Hoechst MRI. Carderm holds the rights to three patents relating to Cardizem CD.

4. At all relevant times herein, Carderm has been, and is now, a partnership as “partnership” is used in Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

5. Respondent Andrx Corporation (“Andrx”) is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Florida, with its office and principal place of business located at 4001 S.W. 47th Avenue, Fort Lauderdale, Florida, 33314. Andrx develops, manufactures, and markets controlled-release pharmaceutical products. Andrx developed a generic or bioequivalent version of Cardizem CD, which has been approved by the FDA for sale in the United States.

6. At all relevant times herein, Andrx has been, and is now, a corporation as “corporation” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

7. Respondents’ acts and practices, including the acts and practices alleged herein, are in or affect commerce as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Federal Regulation of Pharmaceutical Products

8. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., approval by the United States Food & Drug Administration (“FDA”) is required before a company may market or sell a pharmaceutical product in the United States. Approval for a new or brand name drug is sought by filing a New Drug Application (“NDA”) with the FDA.

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9. A generic drug is a product that the FDA has found to be bioequivalent to a brand name drug. Generic drugs are chemically identical to their branded counterparts, but typically are sold at substantial discounts from the branded price. Approval may be sought for a generic version of a brand name drug by filing an Abbreviated New Drug Application (“ANDA”) with the FDA.

10. The FDA maintains a book of Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the “FDA Orange Book”), which lists all patents that the brand name manufacturer asserts relate to each brand name drug. If an applicant intends to market a generic product prior to the expiration of one or more patents relating to a brand name drug, the applicant must certify to the FDA, when appropriate, that the patent or patents listed in the FDA Orange Book are either invalid or not infringed by the generic version of the product (a “Paragraph IV Certification”), and must notify the holder of the approved NDA and the owner of the patent or patents of the filing of the ANDA. If neither the patent holder nor the NDA holder files a patent infringement suit against the ANDA filer within 45 days of receipt of notification of a Paragraph IV Certification, the FDA review and approval process may proceed and, upon FDA approval of the ANDA, the generic product may be marketed. If a patent infringement suit is filed against the ANDA filer within the 45-day period, however, FDA approval of the ANDA is automatically stayed until the earliest of: (i) patent expiration; (ii) a final judicial determination of non-infringement or invalidity in a lawsuit; or (iii) the expiration of a 30-month period from the time the patent holder receives Paragraph IV Certification.

11. The Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the “Hatch-Waxman Act”), as currently implemented by the FDA, provides that the first applicant to submit an ANDA with a Paragraph IV Certification for a generic version of a brand name drug (“ANDA First Filer”) is entitled to a 180-day period of marketing exclusivity (“180-day Exclusivity Period”) before the FDA may grant final approval of any other generic manufacturer’s ANDA

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regarding the same brand name drug. This period does not begin to run until either the generic is commercially marketed or a court enters final judgment that the patents subject to the Paragraph IV Certification are invalid or not infringed. No other generic manufacturer may obtain FDA approval to market its product until the ANDA First Filer's 180-day Exclusivity Period has expired.

Relevant Product And Geographic Market

12. A relevant product market for assessing respondents' anticompetitive conduct is once-a-day diltiazem. Diltiazem belongs to a group of drugs known as "calcium channel blockers," and is used principally to treat high blood pressure (hypertension) and to decrease the occurrence of chronic chest pain ("angina"). Once-a-day diltiazem is a time-release version of diltiazem, in capsule form, that is designed to be taken once every 24 hours. Other calcium channel blockers are not acceptable substitutes for diltiazem for several reasons, including, *inter alia*, the differences in efficacy and side effects, and the risks associated with switching patients from one calcium channel blocker to another. In addition, narrower relevant product markets may be contained within the market for once-a-day diltiazem products. Total U.S. sales of once-a-day diltiazem products amount to roughly \$1 billion per year, with Hoechst MRI's U.S. sales of Cardizem CD, one of the brand name once-a-day diltiazem products, accounting for over \$700 million per year.

13. The relevant geographic market is the United States.

Monopoly Power

14. At all relevant times herein, Hoechst MRI had monopoly power in the U.S. market for once-a-day diltiazem ("the relevant market"), and in narrower markets contained therein. Hoechst MRI distributes the leading once-a-day diltiazem drug, Cardizem CD, which, at all relevant times, accounted for over 70% of total sales in the relevant market.

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15. At all relevant times herein, entry into the relevant market was restricted and unlikely to diminish Hoechst MRI's monopoly power. Before entry could occur, potential entrants were required to, *inter alia*, file an NDA or an ANDA with the FDA, and obtain FDA final approval. At all relevant times, the FDA did not have an NDA accepted for filing for a new once-a-day diltiazem drug. If a new NDA were to be filed with the FDA, final approval would likely take a minimum of 12-18 months. Furthermore, any new once-a-day diltiazem drug introduced pursuant to an NDA would be unlikely to have a significant impact on the market, unless the new drug were bioequivalent to Cardizem CD.

16. At all relevant times herein, FDA final approval of an ANDA for a generic version of Cardizem CD for anyone other than Andrx was blocked. Pursuant to the Hatch- Waxman Act, as interpreted by the FDA, Andrx held the right to a 180-day Exclusivity Period for the sale of a generic version of Cardizem CD. As a result, no company could obtain FDA final approval of an ANDA to market or sell a generic version of Cardizem CD until 180 days after Andrx first sold its product, or until Andrx relinquished or otherwise lost its exclusivity right. Other than Andrx, only two companies had submitted ANDAs for a generic version of Cardizem CD to the FDA: Purepac Pharmaceutical Co. ("Purepac"), a subsidiary of Faulding Inc., and Biovail Corporation International ("Biovail"). Purepac and Biovail did not receive final FDA approval until Andrx's 180-day Exclusivity Period expired in December 1999.

Factual Background

17. In or around September 1995, Andrx filed the first ANDA with the FDA for the manufacture and sale of a generic version of Cardizem CD. In December 1995, Andrx certified to the NDA holder of Cardizem CD that the product covered by its ANDA did not infringe any of the patents covering Cardizem CD. Pursuant to the Hatch-Waxman Act, as currently interpreted, this filing entitled Andrx to a 180-day period during which it would hold the

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exclusive right to market and sell a generic version of Cardizem CD.

18. On January 31, 1996, Hoechst MRI and Carderm filed a lawsuit against Andrx in the U.S. District Court for the Southern District of Florida, alleging infringement of a patent claiming Cardizem CD. Pursuant to the Hatch-Waxman Act, unless the lawsuit was resolved at an earlier date, this lawsuit triggered a 30-month stay of final FDA approval of Andrx's ANDA, until July 1998.

19. In January 1997, Purepac filed an ANDA with the FDA for the manufacture and sale of a generic version of Cardizem CD. On January 31, 1997, Hoechst MRI filed a lawsuit against Purepac in the U.S. District Court for the District of New Jersey, alleging patent infringement. Pursuant to the Hatch-Waxman Act, unless the lawsuit was resolved at an earlier date, this lawsuit triggered a 30-month stay of final FDA approval of Purepac's ANDA, until July 1999.

20. On or about June 19, 1997, Biovail filed an ANDA with the FDA for the manufacture and sale of a generic version of Cardizem CD. Hoechst AG, Hoechst MRI, and Biovail had previously entered into a General Release and Covenant Not to Sue with respect to any claim of patent infringement relating to formulations for a once-daily medicine containing diltiazem.

Anticompetitive Conduct

21. Despite the terms of the General Release and Covenant Not to Sue, representatives of Hoechst MRI met with Biovail in early August 1997, ostensibly to discuss resolution of a potential claim of Hoechst MRI against Biovail for patent infringement relating to Biovail's generic version of Cardizem CD, as well as to discuss development of a new indication or use for the drug Probulcol, a product for which Hoechst MRI held an approved NDA but which was not then being marketed or sold. During the course of these meetings, Hoechst MRI offered to pay Biovail a

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substantial amount of money to complete testing and the FDA approval process for a new Probucol indication. This offer was contingent on Biovail's agreeing to refrain from entering the market with a bioequivalent or generic version of Cardizem CD until at least July 1999. Biovail rejected Hoechst MRI's proposal. Hoechst MRI did not sue Biovail for patent infringement with respect to Biovail's generic or bioequivalent Cardizem CD product.

22. Beginning in late July 1997, representatives of Hoechst MRI and Andrx engaged in discussions of a possible agreement in connection with Hoechst MRI's pending patent infringement lawsuit against Andrx, pursuant to which Andrx would agree to refrain from bringing a generic version of Cardizem CD to market for a specific period of time.

23. On September 24, 1997, Hoechst MRI, Carderm, and Andrx entered into a Stipulation and Agreement. The Stipulation and Agreement did not settle the lawsuit -- indeed, it specifically contemplated that the parties would continue the litigation to final judicial resolution. Instead, Hoechst MRI, Carderm, and Andrx agreed among themselves that Andrx would not enter the market with the generic version of Cardizem CD covered by its ANDA until the earliest of (1) the entry of final judgment in the patent lawsuit, (2) Andrx's obtaining a license from Hoechst MRI under the terms and conditions specified in the Stipulation and Agreement, or (3) Hoechst MRI's providing notice that it intended to license a third party or sell its own bioequivalent or generic version of Cardizem CD. In the Stipulation and Agreement, Andrx also agreed -- at Hoechst MRI's insistence -- to refrain from selling any other bioequivalent or generic version of Cardizem CD, regardless of whether such product would infringe Hoechst MRI's or Carderm's patents. In addition, Andrx agreed not to withdraw its pending ANDA or to relinquish or otherwise compromise any right accruing under its ANDA, including its right to a 180-day Exclusivity Period, until the entry of final judgment in the patent lawsuit.

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24. In exchange for Andrx's various agreements, Hoechst MRI agreed to pay Andrx \$10 million per quarter, beginning upon final FDA approval of Andrx's ANDA (*i.e.*, once Andrx could otherwise have marketed) and continuing until the occurrence of either (1), (2) or (3) described above in Paragraph 23. The Stipulation and Agreement also provided that, should Hoechst MRI lose the patent infringement suit, Hoechst MRI would pay Andrx an additional \$60 million per year for that same time period.

25. The Stipulation and Agreement further provided that, beginning January 9, 2000 or upon the earlier occurrence of any of certain specified events, Andrx would have an option to acquire a license to Hoechst MRI's intellectual property in Cardizem CD. The amount of the royalties to be paid by Andrx to Hoechst MRI would depend on the ultimate outcome of the patent litigation – *i.e.*, Andrx would pay a higher royalty if Andrx ultimately lost the patent infringement litigation.

26. In the event Andrx breached any of its obligations under the Stipulation and Agreement, it would be required to repay all amounts received. For example, if Andrx breached one of its obligations one year after receiving final FDA approval, it would be required to repay \$40 million to Hoechst MRI. In addition, by its terms, the Stipulation and Agreement would terminate in the event of a breach by Andrx, thus extinguishing any right of Andrx to receive an additional payment should it prevail in the patent lawsuit, or to exercise a license should it lose the lawsuit.

27. On July 9, 1998, the FDA granted final approval for Andrx's ANDA for a generic version of Cardizem CD. This approval permitted Andrx to begin the marketing and sale of its generic version of Cardizem CD immediately. In accordance with the terms of the Stipulation and Agreement, Andrx did not begin commercial sale of its generic product. As a result, pursuant to the terms of the Stipulation and Agreement, Hoechst MRI began making quarterly payments of \$10 million to Andrx.

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28. On September 11, 1998, Andrx submitted a Supplemental ANDA to the FDA reflecting a modified formulation of its generic Cardizem CD product. Andrx filed a Paragraph IV Certification, stating its belief that Hoechst MRI had no legitimate basis to claim patent infringement by the product reflected in the Supplemental ANDA. Andrx's Supplemental ANDA received FDA approval on June 8, 1999. On or around that same day, Andrx and HMRI entered into a second agreement, essentially abrogating the Stipulation and Agreement and clearing the way for Andrx to go to market. Andrx began marketing a generic version of Cardizem CD on or around June 23, 1999.

The Effects of Respondents' Conduct

29. The acts and practices of the respondents as herein alleged have had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition and consumers by preventing or discouraging the entry of competition in the form of generic versions of Cardizem CD into the relevant market.

30. Earlier entry of a generic version of Cardizem CD would have had a significant procompetitive impact in the relevant market. Pharmacists generally are permitted, and in some instances required, to substitute FDA-recognized generic drugs for their branded counterparts, without obtaining the prescribing physician's approval. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, managed care plans and Medicaid programs) encourage or insist on the use of generic drugs wherever possible. A generic product can quickly and efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year. For example, respondents' forecasts projected that a generic version of Cardizem CD, sold at 70% of the brand price, would capture roughly 40% of Cardizem CD sales within the first year.

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31. The purpose and intended effect of the \$10 million quarterly payments from Hoechst MRI to Andrx during the term of the Stipulation and Agreement was to provide an incentive for Andrx to refrain both from entering the relevant market, and from taking any steps, including relinquishing its right to a 180-day Exclusivity Period, to permit or facilitate the entry of any other generic manufacturer.

32. By prohibiting Andrx from commencing the commercial sale not only of the product subject to the patent infringement suit, but also of any bioequivalent or generic version of Cardizem CD during the term of the agreement, the Stipulation and Agreement had the purpose and intended effect of deterring Andrx from selling any non-infringing or potentially non-infringing version of its generic Cardizem CD product. As a result, the Stipulation and Agreement was intended to have the effect of delaying substantially Andrx's entry into the relevant market with a generic version of Cardizem CD.

33. By prohibiting Andrx from withdrawing its pending ANDA or relinquishing or otherwise compromising any right accruing under its ANDA, including its right to a 180-day Exclusivity Period, until the entry of final judgment in the patent lawsuit, the Stipulation and Agreement had the purpose or effect of deterring Andrx from relinquishing its eligibility for a 180-day Exclusivity Period under the Hatch-Waxman Act. As a result, the Stipulation and Agreement was intended to have the effect of delaying substantially the entry into the relevant market of generic versions of Cardizem CD produced by other manufacturers.

34. The Stipulation and Agreement is not justified by any countervailing efficiencies.

35. Although the Stipulation and Agreement provided Andrx with the option of selling a generic version of Cardizem CD pursuant to a license from Hoechst MRI at a future date, this did not offset the anticompetitive effects set forth above. Entry by Andrx pursuant to the license was likely to occur, if at all, at a

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later date than would entry by Andrx or another generic manufacturer in the absence of the Stipulation and Agreement. In addition, the license required payment of substantial license fees, subject to the possibility of repayment if Andrx ultimately prevailed in the patent infringement suit. The requirement to pay substantial license fees may have reduced Andrx's incentive to exercise the licensing option. Moreover, entry by Andrx subject to the payment of substantial license fees, even if they may ultimately have been reimbursable, was likely to be competitively less significant than entry without the requirement to pay such fees.

Violations Alleged

36. The Stipulation and Agreement among Hoechst MRI, Carderm and Andrx as a whole, and in particular the specific provisions described in Paragraphs 32 and 33 above, constitute unreasonable restraints of trade in violation of Section 5 of the Federal Trade Commission Act, as amended.

37. Hoechst MRI had the specific intent to preserve its monopoly in the relevant market and narrower markets contained therein, and its actions – including proposing, negotiating and entering into the Stipulation and Agreement among Hoechst MRI, Carderm, and Andrx, and proposing a similar agreement with Biovail – created a dangerous probability that it would accomplish its monopolistic objectives, in violation of Section 5 of the Federal Trade Commission Act, as amended.

38. Hoechst MRI, Carderm, and Andrx acted with the specific intent that Hoechst MRI monopolize the relevant market, and engaged in overt acts described in Paragraphs 21-28 above in furtherance of a conspiracy to monopolize the relevant markets, in violation of Section 5 of the Federal Trade Commission Act, as amended.

39. The acts and practices described above are anticompetitive in nature and tendency and constitute unfair methods of

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competition in violation of Section 5 of the Federal Trade Commission Act, as amended.

NOTICE

Proceedings on the charges asserted against you in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You may file an answer to this complaint. Any such answer must be filed within 20 days after service of the complaint on you. If you contest the complaint's allegations of fact, your answer must concisely state the facts constituting each ground of defense, and must specifically admit, deny, explain, or disclaim knowledge of each fact alleged in the complaint. You will be deemed to have admitted any allegations of the complaint that you do not so answer.

If you elect not to contest the allegations of fact set forth in the complaint, your answer shall state that you admit all of the material allegations to be true. Such an answer will constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the ALJ will file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. Such an answer may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice.

If you do not answer within the specified time, you waive your right to appear and contest the allegations of the complaint. The ALJ is then authorized, without further notice to you, to find that the facts are as alleged in the complaint and to enter an initial decision and a cease and desist order.

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The ALJ will schedule an initial prehearing scheduling conference to be held not later than 7 days after the last answer is filed by any party named as a respondent in the complaint. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

A hearing on the complaint will begin on November 14, 2000 at 10:00 A.M. in Room 532, or such other date as determined by the ALJ. At the hearing, you will have the right to contest the allegations of the complaint and to show cause why a cease and desist order should not be entered against you.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in an adjudicative proceeding in this matter that the respondents are in violation of Section 5 of the Federal Trade Commission Act, as alleged in the complaint, the Commission may order such relief as is supported by the record and is necessary and appropriate including, but not limited to, an order that requires the following:

1. Each Respondent shall cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, from being a party to any Agreement in which one party is an NDA holder for a Drug Product(s), any other party is the ANDA First Filer for the Drug Product(s), and:
 - A. the ANDA First Filer is prohibited by such Agreement from relinquishing, or is subject to a penalty, forfeiture, or

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loss of benefit if it relinquishes, its right to the 180-Day Exclusivity Period; or

- B. the ANDA First Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that could be approved for sale by the FDA pursuant to the ANDA and that is not the subject of a court action alleging patent infringement.

Provided, however, that nothing in this Section shall prohibit Agreements involving the complete transfer of rights in a Drug Product.

2. In any instance where any Respondent is a party to a patent infringement action in which it is either the NDA Holder or the alleged infringer, it shall cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, from being a party to any Agreement in which the parties do not agree to dismiss the litigation, and in which the NDA Holder provides anything of value to the alleged infringer and the alleged infringer agrees to refrain during part or all of the course of the litigation from selling the Drug Product at issue, or any Drug Product containing the same chemical entity(ies) at issue. *Notwithstanding the above, however,* such an Agreement is permissible when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, if: (1) together with the stipulation for a preliminary injunction, the Respondent provides the court with the proposed Agreement, as well as a copy of the Commission’s complaint, order, and Analysis to Aid Public Comment in this matter; (2) the Respondent has provided Notification, as described in Paragraph 4 below, to the Commission at least thirty (30) days prior to submitting the stipulation for a preliminary injunction; (3) the Respondent does not oppose any effort by the Commission to participate, in

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any capacity permitted by the court, in the court's consideration of any such action for preliminary relief; and (4) the court issues an order which incorporates the terms of the Agreement. Nothing in this Paragraph shall be interpreted to prohibit or restrict the right of any Respondent to unilaterally seek relief from the court, without notice to the Commission, including, but not limited to, applying for preliminary injunctive relief or seeking to extend the 30 month stay pursuant to 21 U.S.C. § 355(j)(4)(B)(iii).

3. Each Respondent shall provide Notification as described in paragraph 4 below to the Commission at least thirty (30) days before becoming a party to any Agreement whereby an ANDA First Filer agrees with an NDA holder to refrain from selling any Drug Product under its ANDA for any period of time.
4. The Prior Notification required by Paragraphs 2 and 3 shall be filed with the Secretary of the Commission and shall include the following information, to the extent known, and not subject to any legally recognized privilege: (1) identification of the parties involved in the Agreement; (2) identification of all Drug Products involved in the Agreement; (3) identification of all persons who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the Agreement; (4) a copy of the proposed Agreement; (5) identification of the court, and a copy of the docket sheet, for any legal action which involves either party to the Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and (6) all documents which were prepared by or for any officer(s) or director(s) of any Respondent for the purpose of evaluating or analyzing the Agreement.
5. Each Respondent shall mail a copy of the Commission's complaint and order in this matter, along with a letter from such Respondent's chief executive officer stating that it will abide by the terms of this order, to each of its employees who

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has the authority to enter into agreements concerning the research, development, manufacture, marketing, or sale of a Drug Product.

6. Each Respondent shall take such other measures as are appropriate to correct or remedy, or prevent the recurrence of, the anticompetitive practices engaged in by Respondents.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission, on this sixteenth day of March, 2000, issues its complaint against said Respondents.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having heretofore issued its complaint charging that it had reason to believe that certain acts and practices of Hoechst Marion Roussel, Inc. (“Respondent Hoechst”), Carderm Capital L.P., (“Respondent Carderm”), and Andrx Corporation (“Respondent Andrx”) may have violated Section 5 of the Federal Trade Commission Act, and Respondents having been served with a copy of that complaint, together with a notice of contemplated relief, and Respondents having filed answers denying said charges;

Respondents and counsel for the Commission having thereafter executed an Agreement Containing Consent Order, on the basis of which the matter is being settled; an admission by each Respondent only of the jurisdictional facts set forth in the complaint relating to it (except as modified in the Agreement Containing Consent Order), denying all other allegations; 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 or that any allegation of the complaint is true, other than the jurisdictional facts relating to it set forth in paragraphs 1-4 immediately below (as more fully stated in the Agreement Containing Consent Order); and waivers and other provisions as required by the Commission's Rules; and

The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with § 3.25(c) of its Rules; and

The Commission having thereafter considered the matter and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure prescribed in § 3.25(f) of its Rules, the Commission hereby makes the following jurisdictional findings and enters the following order:

Decision and Order

1. Andrx is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 4001 S.W. 47th Avenue, Fort Lauderdale, Florida, 33314.

2. Hoechst is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 339 Interpace Parkway, P.O. Box 663, Parsippany, New Jersey 07054. Hoechst is, directly or indirectly, a wholly-owned subsidiary of its parent Aventis, S.A., which is incorporated under the laws of the Republic of France with its office and principal place of business at 25 Quai Paul Doumier, 92408 Courbevoie Cedex, France.

3. Carderm is a Delaware limited partnership having its office and principal place of business at Richmond House, 12 Par-la-Ville Road, Hamilton, Bermuda. Carderm is directly or indirectly owned or controlled by Hoechst.

4. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the Commission has determined that this proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that for the purposes of this order, the following definitions shall apply:

A. "Respondent Andrx" means Andrx Corporation, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Andrx, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

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B. “Respondent Hoechst” means Hoechst Marion Roussel, Inc., its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its parent subsidiaries, divisions, groups, and affiliates controlled by Hoechst or its parent, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

C. “Respondent Carderm” means Carderm Capital, L.P., its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Carderm, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

D. “Commission” means the Federal Trade Commission.

E. “180-day Exclusivity Period” means the period of time established by section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j) *et seq.*), as interpreted by the appellate courts at the time of the Agreement.

F. “Agreement” means anything that would constitute an agreement under Section 1 of the Sherman Act or Section 5 of the Federal Trade Commission Act.

G. “ANDA” means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j) *et seq.* as to which the applicant is the ANDA First Filer.

H. “ANDA First Filer” means the party whom the FDA determines is and remains entitled to, or eligible for, a 180-day Exclusivity Period which has not yet commenced running or expired, so long as that status, in the exercise of reasonable diligence at the time of the Agreement, is or would be known to or is believed by the Respondent entering into such Agreement.

I. “Drug Product” means a finished dosage form (*e.g.*, tablet, capsule, or solution) that contains a drug substance, generally, but

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not necessarily, in association with one or more other ingredients, as defined in 21 C.F.R. § 314.3(b).

J. “Effective Date” means the later of (1) the date of entering into the Agreement; or (2) the last date of receipt of each judicial or regulatory approval of the Agreement in the event that such approval is a pre-condition to the Agreement taking effect.

K. “Expiration Date” means the date 180 days (or such other period as is embraced by the definition of 180-day Exclusivity Period) after the date that the ANDA First Filer commences commercial marketing of the Drug Product pursuant to the ANDA, the Reference Drug Product, a Follow-on Drug Product, or any other generic version of the Reference Drug Product or Follow-on Drug Product.

L. “FDA” means the United States Food and Drug Administration.

M. “Follow-on Drug Product” means any Drug Product that (1) is manufactured or licensed by, or for, the same NDA Holder as the Reference Drug Product; (2) involves the same active chemical ingredient or is prescribed for one or more of the same indications as the Reference Drug Product (disregarding for these purposes any new indications of the Follow-on Drug Product); and (3) after the ANDA First Filer has submitted to the FDA its original or initial ANDA (a) receives final FDA approval, (b) is first commercially marketed in the United States, or (c) involves the NDA Holder withdrawing substantial or equivalent marketing or sales efforts from the Reference Drug Product or devoting substantial or additional marketing or sales efforts to the other Drug Product.

N. “NDA” means a New Drug Application, as defined under 21 U.S.C. § 355(b) *et seq.*

O. “NDA Holder” means: (1) the party that received FDA approval to market a Drug Product pursuant to an NDA, (2) a party owning or controlling enforcement of the patent(s) listed in

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the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the “FDA Orange Book”) in connection with the NDA, or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 5% or greater), as well as the licensees, licensors, successors and assigns of each of the foregoing.

P. “Patent Infringement” means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

Q. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

R. “Reference Drug Product” means the Drug Product identified by the ANDA applicant as the Drug Product upon which the ANDA First Filer bases its ANDA.

S. “Relinquishing” means abandoning, waiving, or relinquishing.

II.

IT IS FURTHER ORDERED that Respondents cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, with respect to which Respondent is either an NDA Holder or the ANDA First Filer for such Drug Product(s) from being a party to any Agreement in which one party is an NDA holder, and the other party is the ANDA First Filer, and in which:

A. the ANDA First Filer is prohibited by such Agreement from relinquishing, or is subject to a penalty, forfeiture, or loss of

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benefit if it relinquishes, its right to the 180-Day Exclusivity Period; or

- B. the ANDA First Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that could be approved for sale by the FDA pursuant to the ANDA as to which it is the ANDA First Filer and that is neither the subject of any written claim of Patent Infringement nor supported by a good faith opinion of counsel (the privileged nature of which shall be respected and remain protected), that the Drug Product would be the subject of such a claim if disclosed to the NDA Holder.

Provided, however, that nothing in Paragraph II shall prohibit Agreements where:

- (1) within 20 days of the Effective Date of the Agreement, the ANDA First Filer offers for sale, and as promptly as practicable thereafter, commences commercial marketing of the Drug Product subject to the ANDA, the Reference Drug Product, a Follow-on Drug Product, or any other generic version of the Reference Drug Product or Follow-on Drug Product;
- (2) one of the following two conditions has been satisfied: (a) the 180-day Exclusivity Period, if any, has been triggered and begun to run with respect to the Drug Product subject to the ANDA; or (b) within 10 days of the commercial marketing of a Drug Product other than the one subject to the ANDA, the ANDA First Filer has notified the FDA, in writing, that it will relinquish any and all eligibility for, and entitlement to, a 180-day Exclusivity Period, if any, for the Drug Product subject to the ANDA beyond the Expiration Date. *However*, subparagraphs (1) and (2) shall not apply (or shall be deemed satisfied) if Respondent is a party to an Agreement pursuant to which it engages in conduct described by Paragraphs II.A and/or II.B, but such conduct is pursuant to, or in accordance with, a federal statute, federal appellate court decision, FDA rule, FDA regulation

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or authoritative pronouncement or interpretation of the FDA made or promulgated after the date of this Order; and

- (3) Respondent has provided Notification, as described in Paragraph V below, to the Commission at least thirty (30) days prior to the Effective Date of the Agreement (except that a fewer number of days' notice, but in no event fewer than ten (10), may be given if the ANDA First Filer reasonably believes that such reduced notice will permit it to commence marketing more quickly).

Provided further that nothing anywhere in Paragraph II shall prohibit Agreements involving the complete transfer of rights in a Drug Product or the withdrawal of an ANDA.

III.

IT IS FURTHER ORDERED that, in any instance where a Respondent is a party to a Patent Infringement action in which it is either the NDA Holder or the alleged infringer, it shall cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, from being a party to any Agreement in which (a) the parties do not agree to dismiss the litigation, (b) the NDA Holder provides anything of value to the alleged infringer, and (c) the alleged infringer agrees to refrain during part or all of the course of the litigation from selling the Drug Product at issue, or any Drug Product containing the same active chemical ingredient as the Drug Product. *Notwithstanding the above, however*, such an Agreement is permissible when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, if: (1) together with the stipulation for a preliminary injunction that Respondent provides the court with the proposed Agreement, as well as a copy of the Commission's complaint, order, and Analysis to Aid Public Comment in this matter (which provision may be made to the court in camera or pursuant to any confidentiality order in place in the case); (2) such

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Respondent has provided Notification, as described in Paragraph V below, to the Commission at least thirty (30) days prior to submitting the stipulation for a preliminary injunction; (3) such Respondent does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court's consideration of any such action for preliminary relief (with the Commission giving consideration to participating in such proceeding in the event the Commission determines that such participation will expedite the court's consideration of said preliminary injunction motion); and (4) the court issues an order and the parties' agreement conforms to said order or the Commission determines, at the request of such Respondent, that entering into the stipulation during the pendency of the Patent Infringement action would not raise issues under Section 5 of the Federal Trade Commission Act. Nothing in this paragraph shall be interpreted to prohibit or restrict the right of any Respondent from seeking relief from the court, without notice to the Commission, including, but not limited to, applying for preliminary injunctive relief or seeking to extend, or reduce, the 30-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

IV.

IT IS FURTHER ORDERED that a Respondent shall provide Notification as described in Paragraph V below to the Commission at least thirty (30) days before the Effective Date of any Agreement made after the date the Agreement Containing Consent Order is signed and effective whereby such Respondent is a party and is either an ANDA First Filer or an NDA Holder, and an ANDA First Filer agrees with an NDA Holder to refrain from selling any Drug Product under its ANDA for any period of time, provided that, in the event of litigation between the NDA Holder and the ANDA First Filer, such Respondent is not required to provide Notification for any such Agreement filed with or by the court unless the Agreement results in the dismissal of all or part of said litigation. Such Respondent shall use its best efforts to provide the required Notification in conformity with the 30-day period set forth above.

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V.

The Prior Notification required by Paragraphs III and IV shall be filed with the Secretary of the Commission and shall include the following information, to the extent known and not subject to any legally recognized privilege or immunity: (1) identification of the parties involved in the Agreement; (2) identification of all Drug Products involved in the Agreement; (3) identification of all persons who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the Agreement; (4) a copy of the proposed Agreement; (5) identification of the court, and copy of the docket sheet, for any legal action which involves either party to the Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and (6) all documents which were prepared by or for any officer(s) or director(s) of a Respondent for the purpose of evaluating or analyzing the Agreement.

VI.

IT IS FURTHER ORDERED that each Respondent shall file a verified written report within sixty (60) days after the date this order is issued, annually thereafter for five (5) years on the anniversary of the date this order is issued, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which each Respondent intends to comply, is complying, and has complied with this order. Each 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 this order.

VII.

IT IS FURTHER ORDERED that each 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 corporation, the creation

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or dissolution of subsidiaries or any other change in Respondent that may affect compliance obligations arising out of this order.

VIII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this order and subject to any legally recognized privilege or immunity, and upon written request with reasonable notice to each Respondent, each Respondent shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities, and to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in its possession or under its control relating to compliance with this order; and
- B. To interview officers, directors, employees, agents, and other representatives of each Respondent, who may have counsel present, regarding such compliance issues.

IX.

IT IS FURTHER ORDERED that this order shall terminate on May 8, 2011.

By the Commission.

Analysis

Analysis to Aid Public Comment

Issued when the Commission tentatively approved a proposed consent order on March 30, 2001

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with Hoechst Marion Roussel, Inc. (“HMR”), Carderm Capital, L.P. (“Carderm”), and Andrx Corporation (“Andrx”) to resolve the matters alleged in an administrative complaint issued by the Commission on March 16, 2000. The proposed consent order has been placed on the public record for 30 days to receive comments from interested members of the public. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by HMR, Carderm, or Andrx (collectively “the Respondents”) that they violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true. Respondents deny all other allegations of the complaint.

The Complaint

On March 16, 2000, the Commission issued a complaint alleging that the above respondents entered into an agreement that had the tendency or capacity to restrain competition unreasonably by discouraging generic competition to Cardizem CD. Cardizem CD is a prescription drug manufactured and sold by HMR and is used to treat two chronic conditions that affect millions of Americans: hypertension (high blood pressure) and angina pectoris (chest pain). Andrx is a generic drug manufacturer that developed a generic version of Cardizem CD.

Generic drugs typically are sold at substantial discounts from the price of branded drugs. Generic drugs can have a swift marketplace impact, the complaint states, because pharmacists generally are permitted, and in some instances are required, to substitute lower-priced generic drugs for their branded counterparts, unless the prescribing physician directs otherwise. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, state

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Medicaid programs and many private health plans) encourage or insist on the use of generic drugs wherever possible.

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as “the Hatch-Waxman Act,” to facilitate the entry of lower priced generic drugs while maintaining incentives to invest in new drug development. A company seeking approval from the Food and Drug Administration (“FDA”) to market a new drug must file a New Drug Application (“NDA”) demonstrating the safety and efficacy of its product. In order to receive FDA approval to market a generic version of a brand name drug a company must file an Abbreviated New Drug Application (“ANDA”) demonstrating that its product is bioequivalent to its brand-name counterpart.

The Hatch-Waxman Act establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic drug prior to the expiration of a patent or patents relating to the brand name drug upon which the generic is based. In such cases, the applicant must: (1) certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a “paragraph IV certification”); and (2) notify the patent holder of the filing of the certification. If the holder of the patent rights files a patent infringement suit within 45 days, FDA approval to market the generic drug is automatically stayed for 30 months, under certain circumstances, unless before that time the patent expires or the patent is judicially determined to be invalid or not infringed. This automatic 30-month stay allows the patent holder time to seek judicial protection of its patent rights before a generic competitor is permitted to market its product.

In addition, the Hatch-Waxman Act provides an incentive for generic drug companies to bear the cost of patent litigation that may arise when they challenge invalid patents or design around valid ones. Under current FDA regulations, the Act grants the first company to file an ANDA with a paragraph IV certification a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. No other generic

Analysis

manufacturer may obtain FDA approval to market its product until the first filer's 180-day exclusivity period has expired. At the time the Respondents entered into the challenged agreement in 1997, the governing FDA regulations required that an ANDA applicant successfully defend the patent holder's patent suit in order to be entitled to this exclusivity.

Andrx was the first company to file an ANDA for a generic version of Cardizem CD. It filed a paragraph IV certification with the FDA stating its belief that the product did not infringe any valid patent covering Cardizem CD. In January 1996, HMR sued Andrx for patent infringement. The lawsuit triggered a 30-month stay of final FDA approval of Andrx's generic product, until July 1998.

According to the complaint, HMR and Andrx entered into an agreement in September 1997, in the midst of this patent lawsuit. At the time of the agreement, approximately nine months before the 30-month stay of FDA approval of Andrx's application would expire, the patent lawsuit had already been pending for twenty-one months and both sides had filed numerous dispositive motions with the trial court that had not been acted on. Also by that time, two other companies, Purepac Pharmaceutical Co. and Biovail Corporation International, had filed for FDA approval of a generic Cardizem CD product, neither of which had yet obtained tentative approval from the FDA.

HMR's forecasts, the complaint states, projected that a generic once-a-day diltiazem product would capture roughly 40 percent of Cardizem CD sales within the first year following its launch. Cardizem CD was HMR's largest selling product at the time. Accordingly, the complaint charges, HMR sought to delay Andrx – and all other potential generic competition to Cardizem CD – from entering the market because of the threat they represented to the high profits it was making from Cardizem CD.

The complaint alleges that on September 24, 1997, HMR, Carderm, and Andrx entered into a "Stipulation and Agreement."

Analysis

The Stipulation and Agreement did not settle the lawsuit. Instead, under this agreement, the complaint alleges that Andrx agreed not to enter the market with its generic Cardizem CD product until the earliest of: (1) final resolution of the patent infringement litigation; (2) Andrx's exercise of an option to obtain a license from HMR in the future; or (3) notice by HMR that it would allow entry of another generic Cardizem CD product or market its own generic version of Cardizem CD. According to the complaint, Andrx also agreed to refrain from selling during the patent infringement suit any other bioequivalent or generic version of Cardizem CD. In addition, the complaint alleges that Andrx agreed not to withdraw its pending ANDA or to relinquish or otherwise compromise any right accruing under its ANDA, including its 180-day exclusivity right. In return, the complaint alleges, HMR agreed to pay Andrx \$10 million per quarter during the litigation beginning when Andrx received final FDA approval of its ANDA, unless the litigation was resolved prior to that time. Under the agreement, if HMR lost the patent infringement suit it would pay Andrx an additional \$60 million per year for that same time period. On September 25, 1997, the parties made public disclosures of the existence of the agreement. The Commission's complaint alleges that this agreement, at the time it was entered into, had the potential to affect Andrx's incentive to compete once it received final FDA approval.

In July 1998, upon expiration of the 30-month stay under Hatch-Waxman, Andrx received final FDA approval to market its original formulation of generic Cardizem CD that was subject to the still on-going lawsuit with HMR. Pursuant to the terms of the Stipulation and Agreement, HMR began making quarterly payments of \$10 million to Andrx.

Andrx filed a supplement to its ANDA reflecting a reformulation of its generic Cardizem CD product in September 1998. This reformulation altered the dissolution profile of the Andrx product, which was the basis of the patent dispute between Andrx and HMR. The FDA required Andrx to file a new certification and give notice to HMR of the reformulated product

Analysis

under the Hatch-Waxman procedures described above. Following its analysis of the reformulated product, HMR agreed that it would not assert a patent claim against the reformulated product. By June 1999, Andrx had solved the difficulties it had encountered since the summer of 1997 in consistently manufacturing commercial scale quantities of its formulations of its product in conformity with FDA regulations. Andrx received FDA approval in June 1999 to market its reformulated version of Cardizem CD. On or about the day Andrx received FDA approval of its reformulated product, the Respondents entered into a stipulation dismissing the litigation, with an agreement by Andrx not to sell its original formulation and an agreement by HMR not to sue Andrx for patent infringement on Andrx's reformulated product. The challenged agreement terminated.

On or about June 23, 1999, the federal district court dismissed the patent suit, and Andrx commenced marketing its reformulated generic Cardizem CD product, triggering its 180-day exclusivity period. At that time, Biovail Corporation International had not received tentative FDA approval for its product, and Purepac Pharmaceutical Co. had entered into a licensing arrangement with HMR for manufacture of generic Cardizem CD. Andrx's 180-day exclusivity period expired on December 19, 1999. Purepac launched its generic Cardizem CD product the next day pursuant to a license from HMR. Biovail obtained final FDA approval on December 23, 1999, and launched its product shortly thereafter.

Based on the FTC's investigation, it does not appear that there was any delay in the entry into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD. The agreement terminated in June 1999. It was at that time that Andrx received FDA approval to market, and commenced marketing, a reformulated generic version of Cardizem CD that HMR stipulated did not infringe any HMR patent.

Analysis

The complaint alleges that the challenged agreement was not justified by countervailing efficiencies. In its complaint, the Commission alleged that the presence in the agreement of a licensing provision (permitting Andrx to obtain a license from HMR to market generic Cardizem CD in January 2000, in the event Andrx lost the patent litigation, or if another generic company obtained final FDA approval) did not justify the agreement. The complaint alleges that entry by Andrx under a license, had it occurred, likely would have been later than entry by Andrx or another generic manufacturer absent the agreement.

Finally, the complaint charges that HMR had a monopoly in the market for once-a-day diltiazem, and, that by entering into the agreement with Andrx, HMR sought to preserve its dominance by delaying the entry of Andrx and other generic companies into the market. At the time of the challenged agreement, HMR accounted for 70% of the sales of once-a-day diltiazem in the United States. Other drugs, the complaint alleges, are not effective substitutes for once-a-day diltiazem because they are different in efficacy and side effects, and because of risks associated with switching patients from one treatment to another. In addition, the complaint alleges that HMR and Andrx conspired to monopolize the market for once-a-day diltiazem products. The complaint alleges that HMR and Andrx acted with specific intent that HMR monopolize the market for once-a-day diltiazem, and entered into a conspiracy to achieve that goal. Finally, the complaint charges that the Respondents' agreement otherwise amounts to an unfair method of competition in violation of Section 5 of the FTC Act.

The Proposed Order

In a statement issued at the time of the filing of the complaint in this matter, the members of the Commission stated that cases like this one "must be examined with respect to [their] particular facts," and that the "development of a full factual record in the administrative proceeding . . . will help to shape further the appropriate parameters of permissible conduct in this area, and

Analysis

guide other companies and their legal advisors.”¹ Although the particular agreement challenged in the complaint has been terminated, the Commission believes prospective relief is necessary to prevent a recurrence of the types of agreements covered by the proposed order. Private agreements in which the brand name drug company (the “NDA Holder”) pays the first generic to seek FDA approval (the “ANDA First Filer”), and the ANDA First Filer agrees not to enter the market, have the potential to delay generic competition and raise serious antitrust issues. Moreover, the FDA has observed that the incentives for companies to enter into such arrangements are becoming greater, as the returns to a brand name company from extending its monopoly increasingly exceed the potential economic gains to the generic applicant from its 180 days of market exclusivity.²

The proposed order strikes an appropriate balance, on a prospective basis, between the legitimate interests of the Respondents and the Commission’s concerns with the possible competitive effects of agreements between NDA Holders and ANDA First Filers. By not imposing any broad prohibitions on the Respondents’ ability to compete, the order maintains HMR’s incentive to develop and sell new drug products and Andrx’s incentive to develop and sell generic products that do not infringe valid intellectual property rights held by others. In addition, the order preserves Andrx’s ability to decide for itself whether to market a product in the face of a claim of patent infringement, so long as such decision is otherwise lawful.

¹ Statement of Chairman Pitofsky, Commissioner Anthony, Commissioner Thompson, Commissioner Swindle, and Commissioner Leary concerning Abbott Laboratories and Geneva Pharmaceuticals, Inc., File No. 981-0395 (March 16, 2000).

²FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42882-83 (August 6, 1999).

Analysis

As described more fully below, the proposed order:

- bars (except in certain licensing arrangements) two particular types of agreements between brand name drug companies and potential generic competitors – restrictions on giving up Hatch-Waxman 180-day exclusivity rights and on entering the market with a non-infringing product;
- requires that interim settlements of patent litigation involving payments to the generic company in which the generic company temporarily refrains from bringing its generic product to market, be approved by the court, with notice to the Commission to allow it time to present its views to the court; and
- requires the Respondents to give the Commission written notice 30 days before entering into such agreements in other contexts.

Paragraph II prohibits two kinds of agreements between an NDA Holder and the ANDA First Filer (that is, the party possessing an unexpired right to Hatch-Waxman 180-day exclusivity). Paragraph II.A. bars agreements in which the first company to file an ANDA agrees with the NDA Holder not to relinquish its right to the 180-day exclusivity period (as interpreted by the courts at the time of the agreement). Paragraph II.B. prohibits the ANDA First Filer from agreeing not to develop or market a generic drug product that is not the subject of a claim of patent infringement. The order recognizes, however, that even these types of agreements, in the context of certain licensing arrangements, might not raise competitive concerns. Accordingly, conduct otherwise falling within the conduct described in Paragraph II would not be prohibited where the ANDA First Filer agrees to license and introduce a competitive product to the market, its 180-day exclusivity right is not extended, and the Commission is provided notice.

Paragraph II's focus on agreements between an NDA Holder and the ANDA First Filer does not mean that the Commission

Analysis

believes that there is no risk of competitive harm in other types of agreements. In particular substantial competitive concerns could arise from an agreement in which a generic company (other than the ANDA First Filer) agrees with the NDA Holder to refrain from marketing a non-infringing product. Given the variety of circumstances in which the restraints may arise, however, and the possibility that some legitimate justifications might exist for such arrangements, the Commission believes that it is appropriate at this time to limit the bans in Paragraph II to the described agreements between NDA Holders and ANDA First Filers.

Paragraph III covers certain private agreements involving payments from the NDA Holder to the ANDA First Filer during patent infringement litigation. Generally, the Respondents can enter into such arrangements only if (a) the agreement is presented to the court and embodied in a court-ordered preliminary injunction, and (b) the following other conditions are met: (i) along with any stipulation for preliminary injunction, Respondents provide the court with a copy of the Commission's complaint, order, and the Analysis to Aid Public Comment in this matter, as well as the proposed agreement; (ii) at least 30 days before submitting the stipulation to the court, they provide written notice (as set forth in Paragraph V of the order) to the Commission; and (iii) they do not oppose Commission participation in the court's consideration of the request for preliminary relief.

This part of the proposed order is designed to enhance the court's ability to assess the competitive implications of such agreements. This remedy, in addition to facilitating the court's access to information about the Commission's views, may also make the process more public and thereby may prompt other generic drug manufacturers (or other interested parties) to participate.

Paragraph IV addresses private agreements in which an ANDA First Filer agrees with the NDA Holder not to enter the market. Such situations would include agreements that are part of a final settlement of the litigation, and situations in which no litigation

Analysis

has been brought. In these circumstances, there may be no judicial role in ordering relief agreed to by the Respondents. Thus, the order requires that the Respondents notify the Commission at least 30 days before entering into such agreements. Such notice will assist the Commission because of the potential for competitive harm that these agreements may create. Absent the order, there may be no effective mechanism for the Commission to find out about such agreements.

The form of notice that the Respondents must provide to the Commission under Paragraphs II, III and IV of the order is set forth in Paragraph V. In addition to supplying a copy of the proposed agreement, the Respondents are required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the order requires the Respondents to identify, among other things, all others who have filed an ANDA for a product containing the same chemical entities as the product at issue, and the court that is hearing any relevant legal proceedings involving either party. In addition, the Respondents must provide the Commission with all documents that evaluate the proposed agreement.

The proposed order also contains certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The order will expire in 10 years.

Opportunity for Public Comment

The proposed order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed order and the comments received and will decide

Analysis

whether it should withdraw from the proposed order or make the proposed order final.

By accepting the proposed order subject to final approval, the Commission anticipates that the competitive issues alleged in the complaint will be addressed. The purpose of this analysis is to facilitate public comment on the agreement. It is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.

Complaint

IN THE MATTER OF

DTE ENERGY COMPANY, ET AL.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT*Docket C-4008; File No. 0010067*
Complaint, May 15, 2001--Decision, May 15, 2001

This consent order addresses the merger of a subsidiary of Respondent DTE Energy Company -- a diversified energy holding company whose principal operating subsidiary, The Detroit Edison Company ("Edison"), is a public utility engaged in the generation, transmission, distribution, and sale of electricity in southeastern Michigan, including the Detroit metropolitan area -- and Respondent MCN Energy Group Inc., another diversified energy holding company and the parent of Michigan Consolidated Gas Company ("MichCon"), a natural gas utility serving areas throughout the State of Michigan, including southeastern Michigan. The order, among other things, requires the respondents to divest certain assets -- including an easement over MichCon's local natural gas distribution system permitting the distribution of natural gas in the city of Detroit and all or parts of Macomb, Monroe, Oakland, Washtenaw, and Wayne Counties (the Overlap Area) -- to Exelon Energy Company or to another acquirer approved by the Commission. The order also requires the respondents to appoint an independent third-party auditor with knowledge of the natural gas industry to oversee the easement agreement; to repair and replace all components of the distribution system necessary for the proper operation thereof; and to comply promptly with any request from any customer in the Overlap Area to terminate its transportation or distribution contracts with MCN, without cost or penalty to such customer, to enable such customer to purchase gas distribution or transportation services from Exelon.

Participants

For the Commission: *Dennis F. Johnson, Marc W. Schneider, Constance M. Salemi, Andrew Lee, Mary Rose Emig, Evelyn Boynton, Phillip L. Broyles, Arthur Strong, Elizabeth A. Piotrowski, Roger Boner, John C. Hilke, J. Elizabeth Callison and Daniel O'Brien.*

For the Respondents: *William F. Young, Hunton & Williams, Mary Azcuenaga, Heller Ehrman White & McAuliffe, Ilene*