UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:

Robert Pitofsky, Chairman
Sheila F. Anthony
Mozelle W. Thompson
Orson Swindle
Thomas Leary

In the Matter of HOECHST MARION ROUSSEL, INC., a corporation, CARDERM CAPITAL L.P., a limited partnership, and ANDRX CORPORATION, a corporation.	Docket No. 9293

AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission ("Commission"), has conducted an investigation of certain acts and practices of Hoechst Marion Roussel, Inc. ("Respondent Hoechst"), Carderm Capital, L.P. ("Respondent Carderm") and Andrx Pharmaceuticals, Inc. ("Respondent Andrx"). Respondents Hoechst and Carderm, having been represented by counsel, are willing to enter into this Agreement Containing Consent Order ("Consent Agreement") resolving the allegations contained in the attached complaint. Therefore,

IT IS HEREBY AGREED by and between Respondents Hoechst and Carderm, by their duly authorized officers and their attorneys, and counsel for the Commission that:

1. Respondent 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 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.

2. Respondent 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.

3. Respondents Hoechst and Carderm have been served with a copy of the complaint issued by the Federal Trade Commission charging them with violations of Section 5(a) of the Federal Trade Commission Act, and have filed answers to the complaint.

4. Except as stated in paragraph 1 above, Respondents Hoechst and Carderm admit all the jurisdictional facts relating to them set forth in paragraphs 1-4 of the complaint.

5. Respondents Hoechst and Carderm waive:

   (a) any further procedural steps;

   (b) the requirement that the Commission's Decision and Order ("Decision and Order"), here attached and made a part hereof, contain a statement of findings of fact and conclusions of law;

   (c) all rights to seek judicial review or otherwise to challenge or contest the validity of the Order entered pursuant to this Consent Agreement; and

   (d) any claim under the Equal Access to Justice Act.

6. This Consent Agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this Consent Agreement is accepted by the Commission it, together with the complaint, will be placed on the public record for a period of thirty (30) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this Consent Agreement and so notify Respondents Hoechst and Carderm, in which event it will take such action as it may consider appropriate, or issue and serve its decision in disposition of the proceeding.

7. This Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents Hoechst and Carderm that the law has been violated as alleged in the complaint here attached or that any of the facts alleged in the complaint, other than the jurisdictional facts relating to it in paragraphs 1-4 of the complaint (except as set forth in paragraph 1 above), are true. Respondents Hoechst and Carderm deny the other allegations in the complaint and specifically deny 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 the September 1997 stipulation and agreement between Hoechst and Andrx, at issue delayed consumer access to a generic version of Cardizem CD.

8. This Consent Agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Commission Rule 3.25(f), 16 C.F.R. § 3.25(f), the Commission may, without further notice to Respondents Hoechst and Carderm, (1) issue its decision containing the following Order in disposition of the proceeding, and (2) make information about it public. When so entered, the Order will have the same force and effect and may be altered, modified or set aside in the same manner provided by statute for Commission orders issued on a litigated or stipulated record. The Order shall become final upon service. Delivery of the Decision and Order to Respondents Hoechst's and Carderm's counsel by any means specified in Commission Rule 4.4(a), 16 C.F.R. § 4.4(a), shall constitute service. Respondents Hoechst and Carderm waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the Order, and no agreement, understanding, representation, statement, or interpretation not contained in the Decision and Order or the Consent Agreement may be used to vary or contradict the terms of the Consent Agreement or Decision and Order.

9. By signing this Consent Agreement, Respondents Hoechst and Carderm represent and warrant that they can accomplish the full relief contemplated by this Consent Agreement, and that all of their parents, subsidiaries, affiliates, and successors necessary to effectuate the full relief contemplated by this Consent Agreement shall take the steps required to effectuate the relief contemplated by this Consent Agreement and by the Decision and Order.

10. Respondents Hoechst and Carderm have read the complaint and Decision and Order. They understand that once the Decision and Order has been issued, they will be required to file one or more compliance reports showing how they have complied with the Decision and Order. Respondents Hoechst and Carderm further understand that they may be liable for civil penalties in the amount provided by law for each violation of the Decision and Order after the Decision and Order becomes final.

11. Respondent Hoechst and Carderm are fully authorized to sign on behalf of the entities described in paragraph I.B. and I.C. of the Decision and Order.

Signed this 27th day of November, 2000.

Hoechst Marion Roussel, Inc.

By: _____

Edward H. Stratemeier
Vice President, North America
Legal, Government Affairs, and
Policy

Counsel for Hoechst Marion Roussel, Inc.

By: _____

James M. Spears
Michael L. Koon
Peter D. Bernstein
Shook, Hardy & Bacon LLP

Carderm Capital, L.P.

By: _____

Stephan Petri
Authorized Representative

Counsel for Carderm Capital, L.P.

By: _____

Peter O. Safir
Stacy L. Ehrlich
Kleinfeld, Kaplan and Becker

Federal Trade Commission

By: _____

Markus H. Meier
Bradley S. Albert
Daniel Kotchen
Robin Moore
Seth Silber
Jon M. Steiger

Approved:

David Pender
Deputy Assistant Director

Richard A. Feinstein
Assistant Director

Michael E. Antalics
Deputy Director

Richard G. Parker
Director
Bureau of Competition

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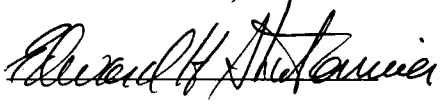
Hoechst Marion Roussel, Inc.

By: 

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By: Stephan Petri

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In the Matter of HOECHST MARION ROUSSEL, INC., a corporation, CARDERM CAPITAL L.P., a limited partnership, and ANDRX CORPORATION, a corporation.	Docket No. 9293 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:

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.

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 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 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 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 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 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.

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 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 ten (10) years from the date this order becomes final.

By the Commission.

Donald S. Clark
Secretary

SEAL

ISSUED:

Analysis to Aid Public Comment

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

The complaint alleges that the 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 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 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." 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 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.

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 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

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[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).

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.

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.

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

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