UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:

Robert Pitofsky, Chairman
Sheila F. Anthony
Mozelle W. Thompson
Orson Swindle
Thomas B. 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 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The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with § 3.25(c) of its Rules; and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: