UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Terrell McSweeny

In the Matter of: **CONCORDIA PHARMACEUTICALS INC., a corporation;** **CONCORDIA HEALTHCARE CORP., a corporation;** **PAR PHARMACEUTICAL, INC., a corporation; and** **PAR PHARMACEUTICAL HOLDINGS, INC., a corporation.**	**Docket No. C-4553**

DECISION AND ORDER
(Concordia)

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of Concordia Pharmaceuticals Inc. and its parent Concordia Healthcare Corp. (collectively "Concordia Entities" or "Respondents") and Par Pharmaceutical, Inc. and Par Pharmaceutical Holdings, Inc. (collectively "Par") and, Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), containing an admission by each Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission that the law has been violated as alleged in such Complaint, or that

the facts alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that Respondents have violated the said Act, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and enters the following Decision and Order ("Order"):

1. Respondent Concordia Pharmaceuticals Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the Country of Barbados, with its office and principal place of business located at Chancery Chambers, Chancery House, High Street Bridgetown, BB Barbados 11128. Concordia Pharmaceuticals Inc. is a subsidiary of Concordia Healthcare Corp.

2. Respondent Concordia Healthcare Corp. is a corporation organized, existing and doing business under and by virtue of the laws of the Province of Ontario, with its office and principal place of business located at 277 Lakeshore Road East, Suite 302, Oakville, Ontario, L6J 1H9.

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

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

A. "Respondents" or "Concordia Entities" means Concordia Pharmaceuticals Inc., Concordia Healthcare Corp., all joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Concordia Pharmaceuticals Inc., or Concordia Healthcare Corp., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "Par" means Par Pharmaceutical Holdings, Inc., 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 One Ram Ridge Road, Chestnut Ridge, NY 10977, and its subsidiaries Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.

C. "505(b)(2) application" means an application filed with FDA pursuant to Section 505(b)(2) of the FFDC Act seeking to market and sell a drug product in the United States.

D. "ANDA" means an Abbreviated New Drug Application filed with the FDA pursuant to Section 505(j) of the FFDC Act, 21 U.S.C.§ 355(j).

E. "Authorized Generic" of a Brand-Name Drug means a drug product that: (a) is manufactured pursuant to (i) the NDA for the Brand-Name Drug, or (ii) an ANDA or a 505(b)(2) application for which the Brand-Name Drug is identified as the reference listed drug; and (b) is sold, offered for sale or distributed by—or on behalf of— the holder of the NDA, but not sold or distributed under the proprietary name of the Brand-Name Drug.

F. "Brand-Name Drug" means a drug product that is manufactured under an approved NDA and is marketed, sold and distributed in the United States under the proprietary name of the drug product. The proprietary name of the drug product is identified in the NDA of the drug product.

G. "Competing ANDA Filer" means a party who controls an ANDA or 505(b)(2) application or who has an exclusive right to sell, offer for sale, or distribute a drug product under such ANDA or 505(b)(2) application if a Respondent controls the NDA for, or has the exclusive right to distribute, the Brand-Name Drug identified as the reference listed drug in the ANDA or 505(b)(2) application.

H. "Concordia License Agreement" means the License Agreement effective September 6, 2013, by and between Concordia Pharmaceuticals, Inc. and Par Pharmaceutical, Inc., attached hereto as Confidential Appendix A.

I. "Entering Into or Attempting to Enter Into" means directly or indirectly entering into, adhering to, participating in, maintaining, implementing, enforcing, inviting, offering or soliciting.

J. "FDA" means the United States Food and Drug Administration.

K. "FFDC Act" means the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 301 et seq.

L. "NDA" means a New Drug Application filed with FDA pursuant to Section 505(b)(1) of the FFDC Act, 21 U.S.C. § 355(b)(1), including all changes or supplements thereto which do not result in the submission of a new NDA.

M. "Orange Book" means the "Approved Drug Products with Therapeutic Equivalence Evaluations" published by the FDA under the FFDC Act, 21 U.S.C. § 301 et seq.

N. "Relevant Employee" means an employee whose responsibilities include, either directly or in a supervisory capacity, business development, pricing, marketing, and sales.

II.

IT IS FURTHER ORDERED that Concordia Pharmaceuticals Inc. shall relinquish all rights to receive, and Respondents shall not receive, the payment of any Additional Supply Price, as defined in Paragraph 3 of the Concordia License Agreement, or any other payment pursuant to the Concordia License Agreement. Not later than ten (10) days after this Order is issued, Respondents shall provide written notice to Par that Concordia Pharmaceuticals Inc. relinquishes all rights to receive any payment of any kind pursuant to the Concordia License Agreement. On the same day that Respondents provide the written notice required by this paragraph to Par, Respondents shall file a copy of such notice with the Secretary of the Commission and shall electronically send a copy of such notice to the Compliance Division of the Bureau of Competition of the Commission at bccompliance@ftc.gov.

III.

IT IS FURTHER ORDERED that in connection with any actions in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, Respondents shall cease and desist from, either directly or indirectly, or through any corporate or other device, Entering Into or Attempting to Enter Into any combination, conspiracy, agreement, or understanding with a Competing ANDA Filer that (1) prohibits or delays in any manner the research, development, manufacture, regulatory approval, marketing or sale of an Authorized Generic and (2) the prohibition or delay in III(1) above is or will be in effect for any period following the expiration of all Patents listed in the patent and exclusivity information section of the Orange Book entry for the Brand-Name Drug.

IV.

IT IS FURTHER ORDERED that

A. For ten (10) years following issuance of this Order, Respondents shall provide a written notice of any agreement with a Competing ANDA Filer that (i) prohibits or delays in any manner the research, development, manufacture, regulatory approval, marketing or sale of an Authorized Generic of a Brand-Name Drug, and (ii) is in effect prior to the expiration of all Patents listed in the patent and exclusivity information section of the Orange Book entry for the Brand-Name Drug (the "Agreement"). Such notice shall:

   1. Be provided thirty (30) days prior to the effective date of the Agreement;

   2. Be filed in writing with the Secretary of the Commission;

   3. Identify all persons and businesses subject to the Agreement;

   4. State when the Agreement will go into effect; and

   5. To the extent known by Respondents, identify all persons and businesses who have filed an ANDA or 505(b)(2) Application for which the relevant Brand-Name Drug is identified as the reference listed drug.

V.

IT IS FURTHER ORDERED that, within five (5) days of issuance of this Order:

A. Respondents shall establish and maintain a compliance program in the United States for the purpose of ensuring compliance with the requirements of this Order.

B. As part of establishing and maintaining a compliance program under this Paragraph, for five years after the date this Order is issued, Respondents shall

1. provide training regarding Respondents' obligations under this Order to their Relevant Employees at least annually, and within thirty (30) days after an individual first becomes a Relevant Employee through hiring or promotion;

2. provide a procedure that enables Relevant Employees to ask questions about, and report violations of, this Order confidentially and without fear of retaliation of any kind;

3. discipline Relevant Employees for failure to comply with this Order; and

4. maintain records showing that Respondents have complied with and are complying with the provisions of this compliance program, including but not limited to, records showing that all Relevant Employees have received all trainings required under this Order during the preceding two (2) years.

VI.

IT IS FURTHER ORDERED that

A. Respondents shall submit to the Commission verified written reports:

1. within thirty (30) days after the date this Order is issued; and

2. one (1) year after the date this Order is issued, and annually for four (4) years thereafter,

which reports shall set forth in detail the manner and form in which Respondents intend to comply, are complying, and have complied with this Order.

B. For purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

1. access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and

2. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

A. any proposed dissolution of a Respondent; or

B. any proposed acquisition, merger or consolidation of a Respondent; or

C. any other change in Respondents, including without limitation, assignment and the creation, sale or dissolution of subsidiaries, if such change may affect compliance obligations arising out of this Order.

VIII.

IT IS FURTHER ORDERED that this Order shall terminate on October 20, 2035.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED: October 20, 2015