UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

Docket No.

DECISION AND ORDER
(Concordia)

arent Concor
Corp. (collectively "Concordia Entities" or "Respondents") and Par Pharmaceutica
Pharmaceutical Holdings, Inc. (collectively "Par"), which are owned by TPG Partn
and, Respondents having been furnished thereafter with a copy of a draft of Compl
Bureau of Competition proposed to present to the Commission for its consideratio
issued by the Commission, would charge Respondents with violation of Section 5
Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having there
an Agreement Containing Consent Order ("Consent Agreement"), containing an ac

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

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.

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 twenty (20) years from the date on which the Order is issued;

By the Commission.

Donald S. Clark
Secretary

SEAL

ISSUED: