
The Federal Trade Commission initiated an investigation of the proposed acquisition by Respondent Hikma Pharmaceuticals PLC of the voting securities of Respondent Custopharm, Inc., a subsidiary of Respondent Water Street Healthcare Partners, LLC. The Commission's Bureau of Competition prepared and furnished to Respondents the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

Respondents and the Bureau of Competition executed an Agreement Containing Consent Order (

7.

- G. “Commission” means the Federal Trade Commission.
- H. “Acquisition” means the proposed acquisition described in the *Agreement and Plan of Merger*, dated September 27, 2021, between Custopharm and Hikma.

applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. "FDA Authorization" also includes an "Investigational New Drug Application" ("IND") filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.

- R. "Monitor" means any monitor appointed pursuant to Section IV of this Order.
- S. "Order Date" means the date on which the final Decision and Order in this matter is issued by the Commission.
- T. "Order" means this Order entered in this action.
- U. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or government entity, and any subsidiaries, divisions, groups, or affiliates thereof.
- V. "Product(s)" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient, or that is the subject of an FDA Authorization.
- W. "Product Approval(s)" means any approvals, reg.29 05 Td(S.)Tj/TT1 1 Tf0 Tc 0 (i)-2 (c)4y, biolf8eiolog (e)-10 (r)(i)-2 (a g(di)-2 (a) 150 (r)(i,7pa) 150 oduc)4 (t)lnf8eiolol Tf2.oval(s thethor9log (

II.

that:

- A. Respondent Hikma shall not acquire, directly or indirectly, through subsidiaries, partnerships, or otherwise, any rights or interests in the TCA Products, TCA Assets, or TCA Business, or the Therapeutic Equivalent or Biosimilar of the TCA Products without the prior approval of the Commission.
- B. For a period lasting until 4 years after the Order Date, Respondent Water Street Healthcare Partners shall not sell, transfer, or otherwise convey, directly or indirectly, any interest in the TCA Assets or TCA Business to any Person, without the prior approval of the Commission.
- C. For a period lasting until 4 years after the Order Date, neither Respondent Water Street Healthcare Partners, Fund IV, nor Long Grove shall terminate the operations of the TCA Business and shall take all actions necessary to maintain the full economic viability, marketability and competitiveness of the TCA Assets and TCA Business.

III.

that:

- A. Respondent Hikma shall not disclose (including to Respondent Hikma's employees), and not use, for any reason or purpose, any Confidential Business Information received or

IV.

that:

- A. At any time after Respondents sign the Consent Agreement, the Commission may appoint a Person to serve as Monitor to observe and report on Respondents' compliance with their obligations as set forth in the Order.
- B. The Respondents and the Monitor may enter into an agreement relating to the Monitor's services. Any such agreement:
 - 1. Shall be subject to the approval of the Commission;
 - 2. Shall not limit, and the signatories shall not construe it to limit, the terms of this Section IV ("Monitor Sections"), and to the extent any provision in the agreement varies from or conflicts with any provision in the Monitor Sections, Respondents and the Monitor shall comply with the Monitor Sections; and
 - 3. Shall include a provision stating that the agreement does not limit, and the signatories shall not construe it to limit, the terms of the Order in this matter, and to the extent any provision in the agreement varies from or conflicts with any provision in the Order, Respondents and the Monitor shall comply with the Order.
- C. The Monitor shall:
 - 1. Have the authority to monitor Respondents' compliance with the obligations set forth in the Order;
 - 2. Act in consultation with the Commission or its staff;
 - 3. Serve as an independent third party and not as an employee or agent of Respondents or of the Commission;
 - 4. Serve without bond or other security;
 - 5. At the Monitor's option, employ such consultants, accountants, attorneys, and other representatives.

2. Shall be deemed to have consented to the selection of the proposed substitute Monitor if, within 10 days of notice by staff of the Commission of the identity of the proposed substitute Monitor, Respondents have not opposed in writing, including the reasons for opposing, the selection of the proposed substitute Monitor; and
 3. May enter into an agreement with the substitute Monitor relating to the substitute Monitor's services that either (a) contains substantially the same terms as the Commission-approved agreement referenced in Paragraph IV.B; or (b) receives Commission approval.
- G. The Commission may on its own initiative or at the request of the Monitor issue such additional order or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.

V.

that:

- A. Respondent Hikma shall notify Commission staff via email at bccompliance@ftc.gov of the Acquisition Date no later than 5 days after the occurrence.
- B. Respondent Long Grove shall submit verified written reports ("compliance reports") in accordance with the following:
 1. Submit compliance reports every 180 days for the next 4 years; and annually thereafter

3. For a period of 5 years after filing a compliance report, each Respondent shall retain all material written communications with each party identified in each compliance report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling Respondent's obligations under this Order during the period covered by such compliance report. Each Respondent shall provide copies of these documents to Commission staff upon request.
4. Each Respondent shall verify its compliance reports in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or another officer or employee specifically authorized to perform this function. Each Respondent shall file its compliance reports with the Secretary of the Commission at ElectronicFilings@ftc.gov and the Compliance Division at bccompliance@ftc.gov, as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a). In addition, Respondent shall provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter.

XI.

that Respondents shall each notify the Commission at least 30 days prior to:

- A. The proposed dissolution of Hikma Pharmaceuticals PLC, Custopharm, Inc., Water Street Healthcare Partners, LLC, Water Street Healthcare Partners III, L.P., Water Street Healthcare Partners IV, L.P., and Long Grove Pharmaceuticals, LLC;
- B. The proposed acquisition, merger or consolidation of Hikma Pharmaceuticals PLC, Custopharm, Inc., Water Street Healthcare Partners, LLC, Water Street Healthcare Partners III, L.P., Water Street Healthcare Partners IV, L.P., and Long Grove Pharmaceuticals, LLC; or
- C. Any other change in Respondents, including assignment and the creation, sale, or dissolution of subsidiaries, if such change may affect compliance obligations arising out of the Order.

~~III~~

that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, upon written request and 5 days' notice to the relevant Respondent, made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters office, the notified Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), in the possession or under the control of the Respondent related to compliance with this Order, which copying services

shall be provided by the Respondent at the request of the authorized representative of the Commission and at the expense of the Respondent; or

- B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XIII.

that the purpose of this Order is to remedy the harm to competition the Commission alleged in its Complaint and ensure Respondent Long Grove will continue to maintain the viability of the TCA Business.

XIV.

that this Order shall terminate July 13, 2032.

By the Commission.

April J. Tabor
Secretary

SEAL
ISSUED: July 13, 2022