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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Lina M. Khan, Chair**
Noah Joshua Phillips
Rebecca Kelly Slaughter
Christine S. Wilson

In the Matter of	)	
	)	
Hikma Pharmaceuticals PLC,	)	
a corporation,	)	
	)	
Custopharm, Inc.,	)	
a corporation,	)	**DECISION AND ORDER**
	)	**Docket No. C-4762**
Water Street Healthcare Partners, LLC,	)	
a limited liability company,	)	
	)	
Water Street Healthcare Partners III, L.P.,	)	
a limited partnership,	)	
	)	
Water Street Healthcare Partners IV, L.P.,	)	
a limited partnership, and	)	
	)	
Long Grove Pharmaceuticals, LLC,	)	
a limited liability company.	)	
	)	

DECISION

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 ("Consent Agreement") containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint, (2) 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 the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true, (3) waivers and other provisions as required by the Commission's Rules, and (4) a proposed Decision and Order.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the said Acts, and that a complaint should issue stating its charges in that respect. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same time, it issued and served its Complaint. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission makes the following jurisdictional findings:

1. Respondent Hikma Pharmaceuticals PLC is a corporation organized, existing, and doing business under, and by virtue of, the laws of the United Kingdom with its executive offices and principal place of business located at 1 New Burlington Place, London, W1S 2HR, United Kingdom.

2. Respondent Custopharm, Inc. is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Texas with its executive offices and principal place of business located at 2325 Camino Vida Roble, Carlsbad, California, 92011.

3. Respondent Water Street Healthcare Partners, LLC is a limited liability company organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware with its executive offices and principal place of business located at 444 West Lake Street, Suite 1800, Chicago, Illinois, 60606.

4. Respondent Water Street Healthcare Partners III, L.P. (Fund III) is a limited partnership organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware with its executive offices and principal place of business located at 444 West Lake Street, Suite 1800, Chicago, Illinois, 60606.

5. Respondent Water Street Healthcare Partners IV, L.P. (Fund IV) is a limited partnership organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware with its executive offices and principal place of business located at 444 West Lake Street, Suite 1800, Chicago, Illinois, 60606.

6. Respondent Long Grove Pharmaceuticals, LLC is a limited liability company organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware with its executive offices and principal place of business located at 9450 W. Bryn Mawr Avenue, Suite 200, Rosemont, Illinois, 60018.

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

ORDER

I. Definitions

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

A. "Hikma" means Hikma Pharmaceuticals PLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Hikma Pharmaceuticals PLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Hikma includes Hikma Pharmaceuticals USA Inc., and Hikma Cali Inc.. After the Acquisition, Hikma will include Custopharm.

B. "Custopharm" means Custopharm, Inc. its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Custopharm, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Custopharm includes Custopharm Topco Holdings, Inc.

C. "Water Street Healthcare Partners" means Water Street Healthcare Partners, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Water Street Healthcare Partners, LLC, including WSHP Pharmaceuticals Holdco, LLC, Long Grove, Fund IV, and Fund III, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

D. "Fund III" means Water Street Healthcare Partners III, L.P., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Water Street Healthcare Partners III, L.P., including Custopharm, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Fund III includes Water Street Healthcare Management III, L.P.

E. "Fund IV" means Water Street Healthcare Partners IV, L.P., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Water Street Healthcare Partners IV, L.P., including Long Grove Pharmaceuticals, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Fund IV includes Water Street Healthcare Management IV, L.P.

F. "Long Grove" means Long Grove Pharmaceuticals, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Long Grove Pharmaceuticals, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

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.

I. "Acquisition Date" means the date relevant Respondents consummate the Acquisition.

J. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes the FDA.

K. "Biosimilar" means any biologic drug product that is highly similar to, and has no clinically meaningful difference from, an existing FDA-approved biologic drug product or that otherwise meets the FDA's criteria for classification as a biosimilar.

L. "Business" means the research, Development, manufacture, commercialization, distribution, marketing, advertisement, importation, and sale of the TCA Product.

M. "Business Information" means all written information, wherever located or stored, relating to or used in the TCA Product Business, including documents, graphic materials, and data and information in electronic format. Business Information includes records and information relating to research and development (including copies of Product Development Reports), manufacturing, process technology, engineering, product formulations, production, sales, marketing (including Product Marketing Materials), logistics, advertising, personnel, accounting, business strategy, information technology systems, customers, customer purchasing histories, customer preferences, delivery histories, delivery routing information, suppliers and all other aspects of the TCA Business. For clarity, Business Information includes any Respondent's rights and control over information and material provided by that Respondent to any other Person. Business Information includes Confidential Business Information.

N. "Confidential Business Information" means all Business Information that is not in the public domain.

O. "Development" means all new chemical entity research, and all studies of the safety or efficacy of a Product, including test method development and stability testing; toxicology; bioequivalency; bioavailability; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting studies of the safety or efficacy of a Product for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, labeling, and sale of a Product (including any government price or reimbursement approvals); Product Approval and registration; and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

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

Q. "FDA Authorization(s)" means all of the following: "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), the

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, registrations, permits, licenses, consents, authorizations, and other regulatory approvals, and pending applications and requests therefor, required by applicable Agencies, related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any FDA Authorization related to that Product.

X. "TCA Products" or "Triamcinolone Acetonide" means the Products in Development or authorized for marketing or sale in the United States pursuant to ANDA No. 213543, and any supplements, amendments, or revisions to this ANDA, and any other Products that are or were in Development or Developed by Custopharm as of September 27, 2021, that are administered via injection and contain, as the active pharmaceutical ingredient, triamcinolone acetonide at a 40mg/ml strength.

Y. "TCA Assets" means all rights, title and interest in the TCA Business related to the TCA Products, including all of the TCA Assets related to the TCA Products.

Z. "TCA Business" means the research, development, manufacture, commercialization, distribution, marketing, advertisement, importation, and sale related to the TCA Product.

AA. "Therapeutic Equivalent" means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product or that otherwise meets the FDA's criteria for such classification.

II. Retention and Operation of Assets

IT IS FURTHER ORDERED 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. Confidentiality

IT IS FURTHER ORDERED 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 maintained by Respondent Hikma, *provided, however,* that Respondent Hikma may disclose or use such Confidential Business Information in the course of:

1. Performing its obligations as permitted under the Order; or

2. Complying with financial reporting requirements, historical record-keeping for audit purposes, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions threatened or brought against the TCA Assets or TCA Business, or as required by law, rule or regulation.

B. Respondent Hikma shall only disclose Confidential Business Information to an employee or any other Person if disclosure is permitted in Paragraph III.A and the employee or other Person has signed an agreement to maintain the confidentiality of such information and not violate the disclosure requirements of this Order.

C. Respondent Hikma shall enforce the terms of this Section III and take necessary actions to ensure that its employees and other Persons receiving Confidential Information comply with its terms, including implementing access and data controls, training of employees, and taking other actions that Respondent Hikma would take to protect its own trade secrets and proprietary information.

IV. Monitor

IT IS FURTHER ORDERED 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 and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;

6. Enter into a non-disclosure or other confidentiality agreement with the Commission related to Commission materials and information received in connection with the performance of the Monitor's duties and require that each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall also enter into a non-disclosure or other confidentiality agreement with the Commission;

7. Notify staff of the Commission, in writing, no later than 5 days in advance of entering into any arrangement that creates a conflict of interest, or the appearance of a conflict of interest, including a financial, professional or personal conflict. If the Monitor becomes aware of a such a conflict only after it has arisen, the Monitor shall notify the Commission as soon as the Monitor becomes aware of the conflict;

8. Report in writing to the Commission concerning Respondents' compliance with the Order 30 days after the Order is issued, and every 90 days for 4 years, thereafter, and at any other time requested by the staff of the Commission; and

9. Unless the Commission or its staff determine otherwise, the Monitor shall serve until Commission staff determines that Respondents have satisfied all obligations under Sections II and III, and files a final report.

D. Respondents shall:

1. Cooperate with and assist the Monitor in performing his or her duties for the purpose of reviewing Respondents' compliance with their obligations under the Order, including as requested by the Monitor, (a) providing the Monitor full and complete access to personnel, information and facilities; and (b) making such arrangements with third parties to facilitate access by the Monitor;

2. Not interfere with the ability of the Monitor to perform his or her duties pursuant to the Order;

3. Pay the Monitor's fees and expenses as set forth in an agreement approved by the Commission, or if such agreement has not been approved, pay the Monitor's customary fees, as well as expenses the Monitor incurs performing his or her duties under the Order, including expenses of any consultants, accountants, attorneys, and other representatives and assistants that are reasonably necessary to assist the Monitor in carrying out his or her duties and responsibilities;

4. Not require the Monitor to disclose to Respondents the substance of the Monitor's communications with the Commission or any other Person or the substance of written reports submitted to the Commission pursuant to the Order; and

5. Indemnify and hold the Monitor harmless against any loss, claim, damage, liability, and expense (including attorneys' fees and out of pocket costs) that arises out of, or is connected with, a claim concerning the performance of the Monitor's duties under the Order, unless the loss, claim, damage, liability, or expense results from gross negligence or willful misconduct by the Monitor.

E. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement, so long as the agreement does not restrict the Monitor's ability to access personnel, information, and facilities or provide information to the Commission, or otherwise observe and report on the Respondents' compliance with the Order.

F. If the Monitor resigns or the Commission determines that the Monitor has ceased to act, has failed to act diligently, or is otherwise unable to continue serving as a Monitor due to the existence of a conflict or other reasons, the Commission may appoint a substitute Monitor. The substitute Monitor shall be afforded all rights, powers, and authorities and shall be subject to all obligations of the Monitor Sections of the Order. The Commission shall select the substitute Monitor, subject to the consent of the Respondents. Respondents:

1. Shall not unreasonably withhold consent to the appointment of the selected substitute Monitor;

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. Compliance Reports

IT IS FURTHER ORDERED 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; and additional compliance reports as the Commission or its staff may request;

2. Each compliance report shall contain sufficient information and documentation to enable the Commission to determine independently whether Respondent Long Grove is in compliance with the Order. Conclusory statements that Respondent Long Grove has complied with its obligations under this Order are insufficient. Respondent Long Grove shall include in its reports, among other information or documentation that may be necessary to demonstrate compliance, a full description of the measures Respondent Long Grove has implemented or plans to implement to ensure that it has complied or will comply with the Order:

   a. market information for the TCA Product including the aggregate size of the TCA market in units and in dollars; the monthly sales in units and in dollars for each market participant to the extent Respondent Long Grove has that information; the market share for each market participant calculated based on units and on dollars; and, to the extent known, an explanation of any significant changes in the total size of the market and any significant adverse impacts to the manufacture or supply, including any adverse impacts to supply by Respondent Long Grove; and

   b. financials for the TCA Business including balance sheets, profit and loss statements, and any other financial statements kept in the ordinary course of business that reflect the financial health of the TCA Business.

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. Change in Respondents

IT IS FURTHER ORDERED 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.

XII. Access

IT IS FURTHER ORDERED 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. Purpose

IT IS FURTHER ORDERED 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. Term

IT IS FURTHER ORDERED that this Order shall terminate 10 years from the date it is issued.

By the Commission.

April Tabor
Secretary

SEAL
ISSUED: