UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Lina M. Khan, Chair

Noah Joshua Phillips Rebecca Kelly Slaughter Christine S. Wilson Alvaro M. Bedoya

In the Matter of)
Hikma Pharmaceuticals PLC,)
a corporation,)
Custopharm, Inc.,)
a corporation,)
Water Street Healthcare Partners, LLC,) Docket No. C-4771
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.)

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Hikma Pharmaceuticals PLC ("Hikma"), a corporation subject to the jurisdiction of the Commission, agreed to acquire Respondent Custopharm, Inc. ("Custopharm"), a subsidiary of Respondent Water Street Healthcare Partners, LLC ("Water Street"), a corporation subject to the jurisdiction of the Commission, in violation 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, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating the charges as follows:

I. RESPONDENTS

- 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 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.

II. JURISDICTION

7. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

III. THE ACQUISITION

8. Pursuant to an Agreement and Plan of Merger dated September 27, 2021, Hikma proposes to acquire Custopharm in a transaction valued at approximately \$375 million ("the Acquisition").

IV. THE RELEVANT MARKETS

- 9. The relevant line of commerce in which to analyze the effects of the Acquisition is the market for generic injectable triamcinolone acetonide ("TCA").
- 10. The United States is the relevant geographic area in which to assess the competitive effects of the Acquisition.

V. THE STRUCTURE OF THE MARKET

11. Injectable TCA is a corticosteroid used for severe skin conditions, allergies, and inflammation. Only two competitors currently market generic injectable TCA: Amneal Biosciences and Teva Pharmaceutical Industries. Custopharm received FDA approval to market its injectable TCA product on January 19, 2022. Hikma has an injectable TCA product in its development pipeline which it expects to launch in the near future.

VI. ENTRY CONDITIONS

12. Entry into the relevant market described in Paragraphs 9 and 10 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would be lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VII. EFFECTS OF THE ACQUISITION

13. The effects of the Acquisition, if consummated, is likely to substantially lessen competition by eliminating future competition between Hikma and Custopharm in the market for injectable TCA thereby (1) increasing the likelihood that the combined entity would forego the launch of Hikma's injectable TCA product in development; and (2) increasing the likelihood that the combined entity would delay, reduce, or eliminate the substantial additional price competition that would have resulted from an additional supplier of this product.

VIII. VIOLATIONS CHARGED

14. The agreement described in Paragraph 8 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and the Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirteenth day of July, 2022, issues its Complaint against said Respondents.

By the Commission.

April J. Tabor Secretary

SEAL