ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter 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
File No. 221-0002, Docket No. C-4762

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Order ("Consent Agreement") from Hikma Pharmaceuticals plc ("Hikma"), Custopharm, Inc. ("Custopharm"), Water Street Healthcare Partners, LLC ("Water Street"), Water Street Healthcare Partners III, L.P. ("Fund III"), Water Street Healthcare Partners IV ("Fund IV"), L.P., and Long Grove Pharmaceuticals, LLC ("Long Grove") (collectively, "Respondents"). The purpose of the Consent Agreement is to remedy the anticompetitive effects that would likely result from Hikma's acquisition of Custopharm ("the Proposed Acquisition"). Pursuant to an agreement dated September 27, 2021, Hikma proposes to acquire Custopharm in a transaction valued at approximately $375 million. As part of the Proposed Acquisition, Custopharm agreed to carve out one of its pipeline products, injectable triamcinolone acetonide ("TCA"), and transferred its TCA assets to Long Grove. The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate 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, by lessening future competition in the U.S. market for injectable TCA. The Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisition.

Under the terms of the proposed Decision and Order ("Order"), Respondent Hikma shall not acquire any rights or interests in TCA products or assets, or any rights or interests in the therapeutical equivalent or biosimilar of TCA products without the prior approval of the Commission. The Order requires Respondents Long Grove and Water Street to operate and maintain in the normal course of business the TCA assets previously operated by Custopharm for a period lasting until four years after the Order date.

The consent agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the consent agreement, modify it, or make final the proposed Order.

I. The Respondents

Respondent Hikma is a multinational pharmaceutical company with headquarters in London, England, and U.S. headquarters in Berkeley Heights, New Jersey. Hikma manufactures both branded and generic pharmaceutical products, including generic injectables.

Respondent Custopharm is incorporated in the State of Texas with its principal place of

business located in Carlsbad, California. Water Street owns a majority of Custopharm. Custopharm develops generic pharmaceutical products but does not have any of its own manufacturing capabilities and manufacturers its products exclusively through contract manufacturers. Those products are then sold through Custopharm's commercial arm, Leucadia Pharmaceuticals.

Respondent Water Street Healthcare Partners, LLC is a private equity firm headquartered in Chicago, Illinois. Water Street is the General Partner of Respondents Fund III and Fund IV.

Respondent Fund III is a private equity fund managed by Water Street located in Chicago, Illinois. Fund III's portfolio includes Custopharm.

Respondent Fund IV is a private equity fund managed by Water Street located in Chicago, Illinois. Fund IV's portfolio includes Long Grove.

Respondent Long Grove is a pharmaceutical company launched in 2019 and headquartered in Rosemont, Illinois. Long Grove is owned by Fund IV.

II. The Relevant Market

In human pharmaceutical markets, prices generally decrease as the number of generic competitors increase. Prices continue to decrease incrementally with the entry of the second, third, fourth, and further pharmaceutical competitors. Accordingly, a reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Acquisition would reduce future competition in the market for injectable TCA. Injectable TCA is a corticosteroid used for severe skin conditions and inflammation. Only three competitors currently market injectable TCA: Bristol-Meyers Squibb, Amneal Biosciences, and Teva Pharmaceutical Industries. Hikma and Custopharm are two of a limited number of suppliers capable of entering the TCA market in the near future.

III. Entry

Entry into the market at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and lengthy.

IV. Competitive Effects

The effect of the Proposed Acquisition, if consummated, is likely to substantially lessen competition by eliminating future competition between Hikma and Custopharm in the market for injectable TCA. The evidence shows that the Proposed Acquisition, absent a remedy, would eliminate an additional independent entrant in the currently concentrated market for injectable

TCA, which would have enabled customers to negotiate lower prices. Customers and competitors have observed—and the pricing data confirms—that the price of pharmaceutical products decreases with new entry even after several other suppliers have entered the market. Thus, absent a remedy, the Proposed Acquisition likely would cause U.S. consumers to pay significantly higher prices for injectable TCA in the future.

V. The Proposed Order

The proposed Order effectively remedies the competitive concerns raised by the Proposed Acquisition for the pharmaceutical product at issue. The proposed Order requires that Hikma not acquire any rights or interests in TCA products or assets, or rights or interests in the therapeutical equivalent or biosimilar of TCA products without the prior approval of the Commission. The proposed Order also requires Water Street and Long Grove to operate and maintain in the normal course of business the TCA assets for a period lasting until four years after the date the Order is issued. The proposed Order also allows the Commission to appoint an individual to serve as Monitor to observe and report on Respondents' compliance with their obligations set forth in the Order.

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The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order to aid the Commission in determining whether it should make the proposed Order final. This analysis is not an official interpretation of the proposed Order and does not modify its terms in any way.