

ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER TO AID PUBLIC COMMENT

In the matter of Aurobindo Pharma Ltd, Aurobindo Pharma USA, Inc., and Lannett Company, Inc., Docket No. C-4834

INTRODUCTION

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Aurobindo Pharma Ltd, Aurobindo Pharma USA, Inc. (collectively, “Aurobindo”), and Lannett Company, Inc. (“Lannett”) (collectively, “Respondents”) to remedy the anticompetitive effects resulting from Aurobindo’s proposed acquisition of Lannett (the “Acquisition”). Aurobindo is one of the world’s largest suppliers of generic pharmaceutical products, and Lannett also develops, manufactures, and sells generic pharmaceutical products within the United States. Aurobindo and Lannett are currently two of a limited number of independent significant competitors in the markets for four generic pharmaceutical products: (1) mycophenolate mofetil oral suspension, (2) generic niacin extended release (“ER”) tablets, (3) generic pilocarpine tablets, and (4) generic rabeprazole sodium delayed release (“DR”) tablets.

The Commission’s Complaint alleges that the 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, and substantially lessen competition in the four relevant generic pharmaceutical markets by eliminating actual, direct, and substantial competition between Aurobindo and Lannett and reducing the number of independent significant competitors, thereby meaningfully increasing the risk that Aurobindo would be able to unilaterally exercise market power in these markets, the remaining competitors would engage in coordination between or among each other, and that customers would be forced to pay higher prices for generic drugs in the relevant pharmaceutical markets.

The Consent Agreement, which contains the proposed Decision & Order (“Order”), will remedy the alleged violations by requiring Respondents to divest all rights and assets related to the four relevant generic pharmaceutical products to Quagen Pharmaceuticals Inc. (“Quagen”). The Commission and Respondents have also agreed to an Order to Maintain Assets that requires Respondents to operate and maintain each divestiture product in the normal course of business until the products are ultimately divested to Quagen.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the Consent Agreement final.

THE PARTIES AND THE TRANSACTION

Aurobindo Pharma Ltd is a company organized, existing, and doing business under and by virtue of the laws of India with its executive offices and principal place of business located at Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad—500032, India. Aurobindo is a global, integrated pharmaceutical company that develops, manufactures, distributes, and commercializes a broad line of generic pharmaceuticals and is one of the largest suppliers of generic pharmaceutical products to the United States.

Aurobindo has operated since 2004 in the United States through its subsidiary, Aurobindo Pharma U.S.A., Inc., headquartered in East Windsor, New Jersey. The company operates two U.S.-based manufacturing facilities: one in East Windsor, New Jersey that produces solid oral dose formulations; and another in Raleigh, North Carolina that produces inhaled products and topical dermatological products.

Lannett Company, Inc. is a 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 1150 Northbrook Drive, Suite 155, Trevose, Pennsylvania 19053. Lannett develops, manufactures, and commercializes generic pharmaceutical products across a variety of therapeutic classes. Lannett manufactures its own products and also operates a contract manufacturing business for other pharmaceutical companies.

Pursuant to a Membership Interest Purchase Agreement dated July 30, 2025, Aurobindo agreed to acquire Lannett in a deal valued at approximately \$250 million. As part of the Acquisition, Aurobindo will acquire Lannett's commercial portfolio, research and development pipeline programs, contract manufacturing business, and U.S.-based generic pharmaceutical manufacturing capabilities.

THE RELEVANT PRODUCTS AND MARKET STRUCTURE

The relevant lines of commerce in which to analyze the effects of the Acquisition are the development, license, manufacture, marketing, distribution, and sale of four pharmaceutical products: (1) generic mycophenolate mofetil oral suspension, (2) generic niacin ER tablets, (3) generic pilocarpine tablets, and (4) generic rabeprazole sodium DR tablets.

Mycophenolate mofetil oral suspension is an immunosuppressant prescribed to help prevent organ transplant rejection. The generic version is marketed in a 200 mg/mL oral generic suspension strength. Though six companies supply generic mycophenolate mofetil oral suspension, the majority of sales are concentrated in Lanett and two other market participants. Aurobindo, which entered the market for mycophenolate in 2025, is the fourth largest competitor in the market.

Niacin ER tablets are used to manage cholesterol levels and to prevent or manage niacin deficiency. Generic niacin ER tablets are available in 500 mg and 1,000 mg strengths. There are

six suppliers of niacin ER tablets in the market, including Aurobindo and Lannett. Aurobindo is the leading supplier of niacin ER tablets in the 500 mg strength, and both Aurobindo and Lannett are significant competitors in the markets for generic niacin ER tablets in both the 500 mg and 1,000 mg strengths.

Generic pilocarpine tablets are used to treat dry mouth, often after radiation therapy for patients with Sjögren's syndrome, which is an autoimmune disease causing the immune system to attack moisture-producing glands. Generic pilocarpine tablets come in 5 mg and 7.5 mg strengths. Lannett is the leading supplier of pilocarpine tablets in the United States, with a share greater than 80 percent for both the 5 mg and 7.5 mg strengths. Six other companies also supply generic pilocarpine in the 5 mg strength, but in the 7.5 mg strength, Lannett and Aurobindo are the only two suppliers in the market.

Rabeprazole sodium tablets are proton pump inhibitors used to reduce stomach acid and are indicated for the treatment of duodenal ulcers, gastroesophageal reflux disease, and Zollinger-Ellison syndrome, a condition where the stomach produces too much acid. Five firms supply generic rabeprazole, including Aurobindo and Lannett. Aurobindo and Lannett are significant competitors in the market for generic rabeprazole tablets in the United States, with over 20 percent share each.

THE RELEVANT GEOGRAPHIC MARKET

The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition. Generic mycophenolate mofetil oral suspension, generic niacin ER tablets, generic pilocarpine tablets, and generic rabeprazole sodium DR tablets are prescription pharmaceutical products approved and regulated by the U.S. Food and Drug Administration ("FDA"). As such, products sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

COMPETITIVE EFFECTS OF THE ACQUISITION

Competition among generic drug manufacturers provides significant benefits for patients and customers. Therapeutically equivalent pharmaceutical products are commoditized, and prices are often inversely correlated with the number of competitors in each market. As the number of suppliers for a therapeutically equivalent drug increases, the price for that drug will decrease due to the direct competition between the existing suppliers and each additional supplier. The Acquisition, however, would likely result in substantial competitive harm by eliminating actual, direct, and substantial competition between Aurobindo and Lannett and reducing the number of independent significant competitors in each of the four relevant generic pharmaceutical markets.

In each of the four markets at issue, Aurobindo and Lannett are two of a limited number of active competitors. While the mycophenolate tablets market appears to have six current suppliers, the majority of the share is concentrated in Lannett and two other market participants. Aurobindo is the fourth largest competitor in this market and has been rapidly gaining share, despite only entering the market last year. Similarly, while the market for niacin ER tablets

appears to have six competitors, most of the sales are concentrated in only four companies, including Aurobindo and Lannett. In the market for pilocarpine tablets, Aurobindo and Lannett are two of a limited number of significant competitors supplying 5 mg tablets and the only competitors supplying the 7.5 mg tablets. Finally, in the market for rabeprazole tablets, the Acquisition would combine two of a limited number of competitors, both of which have significant share of over 20 percent. As a result, the Acquisition would eliminate competition between Aurobindo and Lannett in these markets and reduce the number of competitors in already concentrated markets.

The effects of the Acquisition may also substantially lessen competition in these markets by meaningfully increasing the likelihood that the remaining competitors would engage in coordinated interaction between or among each other post-Acquisition. The generic drug industry has a history of collusion. The Department of Justice and coalitions of state Attorneys General have conducted federal multistate civil antitrust investigations in the generic drug industry, which resulted in charges and complaints alleging several generic drug manufactures violated the antitrust laws by fixing prices for a wide range of generic pharmaceutical products. A history of coordination in an industry creates the risk of future coordination, in particular post-Acquisition, when there will be one fewer significant competitor.

ENTRY CONDITIONS

Entry in the relevant markets 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 be timely due to the time required for drug development and FDA approval requirements, and no other entry is likely to occur that would be sufficient to deter or counteract the competitive harms likely to result from the Acquisition.

THE PROPOSED ORDER AND ORDER TO MAINTAIN ASSETS

The proposed Order effectively remedies the competitive concerns raised by the proposed Acquisition for the four relevant generic pharmaceutical markets at issue. Pursuant to the proposed Order, the parties are required to divest Respondent's rights and assets related to the four products to Quagen. The parties must accomplish these divestitures no later than ten days after the Acquisition is consummated. The provisions of the Consent Agreement ensure that Quagen becomes an independent, viable, and effective competitor in the U.S. markets for the relevant products.

Quagen has the expertise, sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the proposed Acquisition. While it is a smaller generic company, Quagen has significant manufacturing capability and experience marketing and distributing a variety of generic drugs. Quagen is well suited to take on the four products and replace the competition that would be lost as a result of Aurobindo's proposed acquisition of Lannett.

If the Commission determines that Quagen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Respondents to unwind the sale of rights and assets and then divest the affected product to a Commission-approved acquirer within six months of the date the Order becomes final. The Commission has agreed to appoint a Monitor to ensure that Aurobindo and Lannett comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to the buyer. The proposed Order further allows the Commission to appoint a trustee in the event that Aurobindo and Lannett fail to divest the products as required.

* * *

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.