

**UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION**

**COMMISSIONERS: Edith Ramirez, Chairwoman  
Julie Brill  
Maureen K. Ohlhausen  
Terrell McSweeney**

\_\_\_\_\_)  
**In the Matter of** )  
 ) **Docket C-4557**  
**MYLAN N.V.,** )  
**a company.** )  
\_\_\_\_\_)

**COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Mylan N.V. (“Mylan”), a company subject to the jurisdiction of the Commission, has made an offer to acquire the voting securities of Perrigo Company plc (“Perrigo”), a company subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC 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 its charges as follows:

**I. RESPONDENT**

1. Respondent Mylan N.V. is a company organized, existing, and doing business under and by virtue of the laws of the Netherlands, with its principal executive offices located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, United Kingdom AL10 9UL, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: Corporate Secretary, 1000 Mylan Boulevard, Canonsburg, Pennsylvania, 15317.

2. The Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

## **II. ACQUIRED COMPANY**

3. Perrigo is a company organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland, with its principal executive offices located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland.
4. Perrigo is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

## **III. THE PROPOSED ACQUISITION**

5. On September 14, 2015, Mylan launched a tender offer to acquire all outstanding ordinary shares of Perrigo pursuant to a cash-and-stock offer valued according to public sources at approximately \$27 billion (the “Acquisition”).

## **IV. THE RELEVANT MARKETS**

6. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the development, license, manufacture, marketing, distribution, and sale of the following generic pharmaceutical products:
  - a. acyclovir ointment;
  - b. bromocriptine mesylate tablets;
  - c. clindamycin phosphate/benzoyl peroxide gel;
  - d. hydromorphone hydrochloride extended release tablets;

- e. liothyronine sodium tablets;
  - f. polyethylene glycol 3350 over-the-counter (“OTC”) oral solution packets; and
  - g. scopolamine extended release transdermal patches.
7. For the purposes of this Complaint, the United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in the relevant lines of commerce.

## **V. THE STRUCTURE OF THE MARKETS**

8. Acyclovir is used to slow the growth and spread of herpes virus in the body. Two firms, Mylan and Amneal Pharmaceuticals LLC, currently hold approved U.S. Food and Drug Administration (“FDA”) Abbreviated New Drug Applications (“ANDAs”) for generic acyclovir 5% ointment. Allergan plc (“Allergan”) also sells the authorized generic version for acyclovir 5% ointment. Perrigo is one of a limited number of suppliers likely to enter the generic acyclovir market in the near future. The Acquisition would reduce the number of likely future suppliers for generic acyclovir 5% ointment.
9. Bromocriptine mesylate is a dopamine agonist used to treat Type 2 diabetes, pituitary tumors, Parkinson’s disease, neuroleptic malignant syndrome, and hyperprolactinemia. In the United States, three companies have approved ANDAs for generic bromocriptine mesylate 2.5 mg tablets: Mylan; Perrigo; and Sandoz AG. The Acquisition would reduce the number of firms capable of supplying generic bromocriptine mesylate 2.5 mg tablets from three to two.
10. Clindamycin phosphate 1%/benzoyl peroxide 5% gel is a combination antibiotic and drying agent used to stop the bacterial infection that causes acne. In the United States, only Mylan markets generic clindamycin phosphate 1%/benzoyl peroxide 5% gel. Perrigo recently received ANDA approval from the FDA and expects to begin supplying generic clindamycin phosphate 1%/benzoyl peroxide 5% gel in the near future. The Acquisition would combine the only two approved ANDA holders for generic clindamycin phosphate 1%/benzoyl peroxide 5% gel.
11. Hydromorphone hydrochloride is an analgesic used to treat moderate to severe pain in narcotic-tolerant patients. In the United States, only Perrigo and Allergan hold approved ANDAs to sell generic hydromorphone hydrochloride extended release tablets in the 8 mg, 12 mg, and 16 mg strengths. Mallinckrodt plc also sells an authorized generic version of hydromorphone hydrochloride extended release tablets. Mylan is one of a limited number of suppliers likely to enter the market in the near future. As a result, the

Acquisition would reduce the number of future suppliers of generic hydromorphone hydrochloride extended release tablets in the 8 mg, 12 mg, and 16 mg strengths.

12. Liothyronine sodium is a synthetic thyroid hormone used to treat hypothyroidism and to treat or prevent enlarged thyroid glands. Currently, three suppliers provide 0.005 mg, 0.025 mg, and 0.05 mg generic liothyronine sodium tablets: Mylan; Perrigo; and SigmaPharm Laboratories, LLC. The Acquisition would increase concentration in this market and reduce the number of suppliers of 0.005 mg, 0.025 mg, and 0.05 mg generic liothyronine sodium tablets from three to two.
13. Polyethylene glycol 3350 (“PEG 3350”) is a laxative used to treat occasional constipation. The market for generic PEG 3350 OTC oral solution 17gm packets is highly concentrated with only Mylan, Perrigo, and Gavis Pharmaceuticals, LLC actively supplying the market. The Acquisition would therefore reduce the number of suppliers in this market from three to two.
14. Scopolamine prevents nausea and vomiting associated with motion sickness and recovery from anesthesia and surgery. Novartis AG sells a branded scopolamine extended release (1 mg/72 hours) transdermal patch, Transderm Scop. Only Perrigo holds an approved ANDA to sell generic scopolamine extended release (1 mg/72 hours) transdermal patch. Mylan is one of a limited number of suppliers likely to enter this market in the near future. As a result, the Acquisition would reduce the number of likely future suppliers of generic scopolamine extended release (1 mg/72 hours) transdermal patches.

## **VI. ENTRY CONDITIONS**

15. Entry into the relevant markets described in Paragraphs 6 and 7 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 delay entry by at least two years. 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**

16. The effects of the Acquisition, if consummated, may be to substantially lessen competition in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Mylan and Perrigo and reducing the number of independent significant competitors in the markets for generic (1) bromocriptine mesylate tablets; (2) clindamycin phosphate/benzoyl peroxide gel; (3) liothyronine sodium tablets; and (4) polyethylene glycol 3350 OTC oral solution packets, thereby: (a) increasing the likelihood that Mylan would be able to unilaterally exercise market power in these markets; (b) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (c) increasing the likelihood that customers would be forced to pay higher prices; and
- b. by eliminating future competition between Mylan and Perrigo and reducing the number of generic competitors in the markets for (1) acyclovir ointment; (2) hydromorphone hydrochloride extended release tablets; and (3) scopolamine extended release transdermal patches, thereby: (a) increasing the likelihood that the combined entity would forego or delay the launch of these products, and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of these products.

### **VIII. VIOLATIONS CHARGED**

- 17. The Acquisition described in Paragraph 5, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

**WHEREFORE, THE PREMISES CONSIDERED,** the Federal Trade Commission on this second day of November, 2015, issues its Complaint against said Respondent.

By the Commission.

Donald S. Clark  
Secretary

SEAL: