MERGER ANTITRUST LAW

Unit 15: Mylan/Perrigo

(Full Set of Case Materials)

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Dale Collins

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FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

FTC Requires Mylan to Sell Rights to Seven Generic Pharmaceuticals as a Condition of Acquiring Perrigo Company

Divestitures Will Preserve Competition in U.S. Markets for Seven Generic Drugs

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FOR RELEASE

November 3, 2015

TAGS: Bureau of Competition | Competition

Mylan N.V. has agreed to sell the rights and assets related to seven generic drugs in order to settle FTC charges that its proposed acquisition of Perrigo Company plc would be anticompetitive.

Both companies market generic drugs globally, and according to the FTC complaint, as originally proposed, the acquisition would likely harm competition in U.S. markets for seven generic pharmaceutical products. The settlement order preserves competition by requiring Mylan to divest the rights and assets in these product markets to the New Jersey-based generic pharmaceutical company Alvogen Group Inc.

The complaint alleges that the proposed acquisition would likely have harmed current competition in U.S. markets for four generic drugs. In these markets, both Mylan and Perrigo either are currently selling the drugs, or have approval of the Food and Drug Administration to do so:

- **Bromocriptine mesylate** is used to treat conditions including type 2 diabetes and Parkinson's disease.
- **Clindamycin phosphate/benzoyl peroxide** is used to treat acne.
- **Liothyronine sodium** is used to treat hypothyroidism and to treat or prevent enlarged thyroid glands.
- **Polyethylene glycol 3350** is a laxative used to treat occasional constipation.

The FTC's settlement also will preserve future competition for three generic drugs. According to the complaint, the proposed acquisition would eliminate at least one likely future entrant from a very limited pool of future entrants in each of these markets:

- **Acyclovir** is used to slow the growth and spread of the herpes virus in the body.
- **Hydromorphone hydrochloride** is used to treat moderate to severe pain in narcotic-tolerant patients.
- **Scopolamine** prevents symptoms associated with motion sickness and helps patients recover from anesthesia and surgery.

The proposed buyer, Alvogen, has the necessary resources, financial and technical capabilities, and experience marketing generic pharmaceutical products to replace successfully the competition that otherwise would have been lost through the proposed acquisition.

To ensure that the divestitures succeed, the proposed order requires Mylan to provide Alvogen with transitional services, including technical assistance. Further details about the divestitures are set forth in the analysis to aid public comment for this matter.

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The Commission vote to issue the complaint and accept the proposed consent order for public comment was 4-0. The FTC will publish the consent agreement package in the Federal Register shortly. The agreement will be subject to public comment for 30 days, beginning today and continuing through December 3, 2015, after which the Commission will decide whether to make the proposed consent order final. Comments can be filed electronically or in paper form by following the instructions in the "Supplementary Information" section of the Federal Register notice.

NOTE: The Commission issues an administrative complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $16,000 per day.

The FTC's Bureau of Competition works with the Bureau of Economics to investigate alleged anticompetitive business practices and, when appropriate, recommends that the Commission take law enforcement action. To inform the Bureau about particular business practices, call 202-326-3300, send an e-mail to antitrust@ftc.gov, or write to the Office of Policy and Coordination, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Ave., NW, Room CC-5422, Washington, DC 20580. To learn more about the Bureau of Competition, read Competition Counts. Like the FTC on Facebook, follow us on Twitter, and subscribe to press releases for the latest FTC news and resources.

PRESS RELEASE REFERENCE:
FTC Approves Modified Consent Order for Mylan N.V.

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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

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:

ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Mylan N.V., File No. 151-0129

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Mylan N.V. ("Mylan") that is designed to remedy the anticompetitive effects resulting from Mylan's acquisition of Perrigo Company plc ("Perrigo"). Under the terms of the proposed Consent Agreement, Mylan is required to divest to Alvogen, Inc. ("Alvogen") all of its rights and assets to the following generic pharmaceutical products: (1) acyclovir ointment; (2) bromocriptine mesylate tablets; (3) clindamycin phosphate/benzoyl peroxide gel; (4) hydromorphone hydrochloride extended release tablets; (5) liothyronine sodium tablets; (6) polyethylene glycol 3350 over-the-counter ("OTC") oral solution packets; and (7) scopolamine extended release transdermal patches.

The proposed 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 proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order ("Order").

On September 14, 2015, Mylan launched a hostile tender offer to gain a controlling interest in Perrigo. 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 current and future competition in seven generic pharmaceutical markets in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

I. The Products and Structure of the Markets

A generic pharmaceutical drug contains the same active ingredient as the brand name product, but typically at a much more affordable price. Pharmaceutical companies usually launch generic versions of drugs after a branded product loses its patent protection. When only one generic product is available, the price for the branded product typically acts as a ceiling above which the generic manufacturer cannot price its product. During this period, the branded product competes directly with the generic. Once multiple generic suppliers enter a market, the branded drug manufacturer usually ceases to provide any competitive constraint on the prices for generic versions of the drug. Rather, generic suppliers compete only against each other.

Mylan's proposed acquisition of Perrigo will lessen competition in seven concentrated generic pharmaceutical product markets by reducing the number of current or future suppliers competing in each market. The proposed acquisition will reduce current competition in four generic pharmaceutical markets: (1) bromocriptine mesylate tablets; (2) clindamycin phosphate/benzoyl peroxide gel; (3) liothyronine sodium tablets; and (4) polyethylene glycol 3350 OTC oral solution packets.

- Bromocriptine mesylate is a dopamine agonist used to treat Type 2 diabetes, pituitary tumors, Parkinson's disease, neuroleptic malignant syndrome, and hyperprolactinemia. The market for generic 2.5 mg bromocriptine mesylate tablets is highly concentrated with only three current suppliers: Mylan, Perrigo, and Sandoz AG. Absent a remedy, the proposed transaction would consolidate the market from three to two suppliers.

- Clindamycin phosphate/benzoyl peroxide gel is a combination antibiotic and drying agent used to stop the bacterial infection that causes acne. Today, only Mylan supplies the market with generic clindamycin phosphate 1%/benzoyl peroxide 5% gel. Perrigo recently received FDA approval for generic clindamycin phosphate 1%/benzoyl peroxide 5% gel and is poised to start supplying the market in the near future. As a result, the proposed transaction would reduce the number of generic clindamycin phosphate 1%/benzoyl peroxide 5% gel suppliers from two to one.

- Liothyronine sodium is a synthetic thyroid hormone used to treat hypothyroidism and to treat or prevent enlarged thyroid glands. Currently, only three suppliers provide generic liothyronine sodium tablets in the 0.005 mg, 0.025 mg, and 0.05 mg strengths: Mylan, Perrigo, and SigmaPharm Laboratories, LLC. The proposed transaction would further consolidate an already highly concentrated market, leaving two suppliers post-transaction.

- Polyethylene glycol 3350, a laxative, is an OTC oral solution packet used to treat occasional constipation. In the 17 gm/packet OTC market, Mylan, Perrigo, and Gavis Pharmaceuticals, LLC, are the only active suppliers in the market. As a result, the proposed transaction would consolidate the number of active suppliers of generic polyethylene glycol 3350 OTC oral solution packets from three to two.

Additionally, the proposed acquisition will reduce future competition in three generic pharmaceutical markets: (1) acyclovir ointment; (2) hydromorphone hydrochloride extended release tablets; and (3) scopolamine extended release transdermal patches. In each of these markets, either Mylan or Perrigo is a likely new entrant in the near future. Without a remedy, the proposed acquisition would eliminate an independent entrant into each market, likely depriving customers of the significant cost savings that result when an additional generic supplier enters a concentrated market.

- Acyclovir ointment is a topical product used to slow the growth and spread of the herpes virus. Mylan and Amneal Pharmaceuticals LLC currently hold ANDAs and supply acyclovir 5% ointment. Allergan plc ("Allergan") also sells an authorized generic version of acyclovir 5% ointment. Perrigo is one of a limited number of suppliers likely to enter this market in the near future.

- Hydromorphone hydrochloride is an analgesic used to treat moderate to severe pain in narcotic-tolerant patients. Perrigo and Allergan hold ANDAs for 8 mg, 12 mg, and 16 mg extended release tablets. In addition, Mallinckrodt plc markets an authorized generic

version of hydromorphone hydrochloride extended release tablets. Mylan is one of a limited number of suppliers likely to enter this market in the near future.

- Scopolamine transdermal patches prevent nausea and vomiting associated with motion sickness and recovery from anesthesia and surgery. Novartis AG currently markets the branded version, Transderm Scop, which is available as a 1 mg/72 hour extended release transdermal patch. Perrigo holds the only approved ANDA for the generic version of Transderm Scop. Mylan is one of a limited number of other suppliers likely to enter this market in the near future. As there is no generic version of Transderm Scop on the market today, it is likely that the price for scopolamine transdermal patches would significantly decrease with the onset of generic competition. Without a remedy, the proposed acquisition would eliminate the price reductions that would likely have accompanied Mylan's independent entry into this market.

II. Entry

Entry into each of these generic pharmaceutical markets 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 United States Food and Drug Administration ("FDA"), is costly and lengthy.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating current or future competition between Mylan and Perrigo in these seven concentrated markets. In each of these markets, Mylan and Perrigo are two of a limited number of current or likely future suppliers in the United States. Market participants characterize each of the markets as a current or likely future commodity market, in which the number of generic suppliers has a direct impact on pricing. Customers and competitors have observed that the price of generic pharmaceutical products decreases with new entry even after several suppliers have entered the market. Removal of an independent generic pharmaceutical supplier from the relevant markets in which Mylan and Perrigo currently compete likely would result in significantly higher prices post-acquisition. Similarly, the elimination of a future independent competitor would prevent the price decreases that are likely to result from the firm's entry. Thus, absent a remedy, the proposed acquisition will likely cause U.S. consumers to pay significantly higher prices for these generic drugs.

IV. The Consent Agreement

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in each relevant market. Under the Consent Agreement, Mylan is required to divest to Alvogen its rights to the seven relevant products. Alvogen is an international pharmaceutical company, with commercial operations in thirty-four countries. Its business focuses on developing, manufacturing, and distributing generic, branded, and OTC

pharmaceutical products. Mylan must accomplish the divestitures to Alvogen and relinquish its rights to these products no later than thirty days after the proposed acquisition is consummated.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that Alvogen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Mylan to unwind the sale of rights to Alvogen and to divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee if Mylan fails to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Mylan to take all action to maintain the economic viability, marketability, and competitiveness of the products to be divested until such time that they are transferred to a Commission-approved acquirer. Mylan must provide transitional services to Alvogen to assist it in establishing independent manufacturing capabilities. These transitional services include technical assistance to manufacture the divestiture products in substantially the same manner and quality employed or achieved by Mylan, and advice and training from knowledgeable Mylan employees. Mylan must also provide Alvogen with a supply of the divested products while Mylan transfers manufacturing technology to Alvogen or its designated manufacturer. The goal of the transitional services is to ensure that Alvogen will be able to operate independent of Mylan in the manufacture and sale of the divested products. Nothing in the Consent Agreement, however, precludes Alvogen from sourcing active pharmaceutical ingredients or other divestiture product inputs from Mylan on a negotiated basis.

As Alvogen was unable to perform due diligence on the Perrigo products at issue, Mylan divested its own on-market, generic acyclovir ointment product rather than Perrigo's product in development. Because the competition that is preserved by the proposed Consent Agreement will only occur when the Perrigo product is launched, the proposed Order permits Mylan to retain the right to sell acyclovir ointment through a license from Alvogen until thirty days after Mylan receives approval for the Perrigo ANDA, but for no longer than three years. This provision is designed to permit Mylan to remain an active market participant pending the approval of Perrigo's acyclovir ointment ANDA but also ensures Mylan's continued incentive to develop and launch the Perrigo product.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.