

Complaint

IN THE MATTER OF

MYLAN N.V.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4557; File No. 151 0129**Complaint, November 2, 2015 – Decision, February 19, 2016*

This consent order addresses the acquisition by Mylan N.V. of certain assets of Perrigo Company plc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening current and future competition in seven generic pharmaceutical markets in the United States. The consent order requires Mylan to divest all of its rights and assets to (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 oral solution packets; and (7) scopolamine extended release transdermal patches to Alvogen, Inc.

Participants

For the *Commission*: Marc S. Lanoue, Eric Olson, Jasmine Y. Rosner, and David Von Nirschl.

For the *Respondent*: Yonatan Even and Christine Varney, Cravath, Swaine & Moore LLP.

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.

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§ 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”).

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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.

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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.

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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

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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.

Order to Maintain Assets

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Mylan N.V. (“Respondent” or “Mylan”) of the voting securities of Perrigo Company plc (“Perrigo”), and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations 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

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

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,

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and the Order to Maintain Assets, as follows:
Corporate Secretary, 1000 Mylan Boulevard,
Canonsburg, Pennsylvania, 15317.

2. 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.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Mylan” or “Respondent” means: Mylan N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Mylan N.V. (including, without limitation, Mylan Pharmaceuticals Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include Perrigo.
- B. “Perrigo” means: Perrigo Company plc, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Perrigo Company plc, and the

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respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- C. “Commission” means the Federal Trade Commission.
- D. “Decision and Order” means the:
 - 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 - 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- E. “Divestiture Product Business(es)” means the Business of the Respondent within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products to the extent that such Business is owned, controlled, or managed by the Respondent and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondent.
- F. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- G. “Transition Period” means the period beginning on the date this Order to Maintain Assets is issued and ending on the earlier of the following dates: (i) the date on which the Acquirer directs the Respondent to cease the marketing, distribution, and sale of the Divestiture Product(s) acquired by that Acquirer; (ii) the date on which the Acquirer commences the marketing, distribution, and sale of such Divestiture Product(s); or (iii) the date four (4) months after the Closing Date for such Divestiture Product(s).

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- H. “Orders” means the Decision and Order and this Order to Maintain Assets.

II.**IT IS FURTHER ORDERED** that:

- A. Until Respondent fully transfers and delivers each of the respective Divestiture Product Assets to an Acquirer, Respondent shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Divestiture Product Assets except for ordinary wear and tear. Respondent shall not sell, transfer, encumber or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the related Divestiture Product Businesses.
- B. Until Respondent fully transfers and delivers each of the respective Divestiture Product Assets to an Acquirer, Respondent shall maintain the operations of the related Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the full economic marketability, viability, and competitiveness of such Divestiture Product Businesses and shall use its best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; High Volume Accounts; end-use customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses.

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Respondent's responsibilities shall include, but are not limited to, the following:

1. providing each of the respective Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for such Divestiture Product Business;
2. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by Respondent including, but not limited to, all research, Development, manufacturing, distribution, marketing and sales expenditures;
3. providing such resources as may be necessary to respond to competition against each of the Divestiture Products and/or to prevent any diminution in sales of each of the Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Product Assets to an Acquirer;
4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products that were marketed or sold in the United States prior to the date the Consent Agreement was signed by the Respondent, at the related High Volume Accounts;
5. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such Divestiture Product Business; and

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6. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such Divestiture Product Business by Respondent as of the date the Consent Agreement was signed by Respondent.
- C. Until Respondent fully transfers and delivers each of the respective Divestiture Product Assets to an Acquirer, Respondent shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall:
1. for a period of twelve (12) months beginning on the Closing Date or until the hiring of twenty (20) Divestiture Product Core Employees by that Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s);"
 2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the

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time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use, and (iv) destroy or return the information without retaining copies at such time as the specified and permitted use ends;

3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, Respondent shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

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provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondent from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law); and
5. for a period of one (1) year beginning on the Closing Date, not, directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or hire any Divestiture Product Employee;

provided, however, Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for

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employment with the Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that the Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts the Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondent;

provided further, however, that nothing in this Order shall be construed to require Respondent to terminate the employment of any employee or to prevent Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition.

- E. During the Transition Period, with respect to each Divestiture Product that is marketed or sold in the United States before the Closing Date, Respondent, in consultation with the Acquirer of a particular Divestiture Product(s) (“relevant Acquirer”), for the purposes of ensuring an orderly marketing and distribution transition, shall:
1. develop and implement a detailed transition plan to ensure that the commencement of the marketing, distribution and sale of such Divestiture Products by the relevant Acquirer is not delayed or impaired by the Respondent;
 2. designate employees of Respondent knowledgeable about the marketing, distribution and sale related to each of the Divestiture Products who will be responsible for communicating directly with the relevant Acquirer, and the Interim Monitor (if one has been appointed), for the

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purposes of assisting in the transfer of the Business related to the Divestiture Products to that Acquirer;

3. maintain and manage inventory levels of the Divestiture Products in consideration of the marketing and distribution transition to the relevant Acquirer;
4. continue to market, distribute and sell the Divestiture Products in the United States;
5. beginning on the Acquisition Date, allow the relevant Acquirer access at reasonable business hours to all Confidential Business Information related to the Divestiture Products and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products that contain such Confidential Business Information pending the completed delivery of such Confidential Business Information to that Acquirer;
6. beginning on the Acquisition Date, provide the relevant Acquirer with a listing of inventory levels (week of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler or distributor) on a regular basis and in a timely manner;
7. beginning on the Acquisition Date, provide the relevant Acquirer with anticipated reorder dates for each customer on a regular basis and in a timely manner; and
8. establish projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the relevant Acquirer in an efficient and timely manner.

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- F. Pending divestiture of the Divestiture Product Assets, Respondent shall:
1. not use, directly or indirectly, any Confidential Business Information related to the Business of the Divestiture Products other than as permitted by the Orders or as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondent's obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
 2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except: (i) the Acquirer of the particular Divestiture Product Assets; (ii) other Persons authorized by that Acquirer to receive such information (*e.g.*, employees of the Respondent responsible for the Contract Manufacture of a Divestiture Product on behalf the Acquirer); (iii) the Commission; (iv) the Interim Monitor (if any has been appointed); or (v) Persons as are necessary to give effect to the Mylan Limited License;
 3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products; *provided however*, that, with respect to the Acyclovir Products that are the subject of the Mylan Limited License, this provision shall only apply to the Confidential Business Information

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related to the ongoing marketing or sales of the Acyclovir Products by the Acquirer (*e.g.*, information on purchases made by the Acquirer under any agreement with the Respondent to Contract Manufacture) and shall not apply to historical Confidential Business Information (*i.e.*, such information as is generated prior to the Closing Date); and

4. institute procedures and requirements to ensure that the above-described employees:
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
 - b. do not solicit, access or use any Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- G. Not later than thirty (30) days after the earlier of (i) the Closing Date or (ii) the date this Order to Maintain Assets is issued by the Commission, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information.
- H. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to the relevant Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an

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officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondent shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

- I. Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions with respect to Confidential Business Information, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets.

The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer, to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Product Assets except for ordinary wear and tear.

III.

IT IS FURTHER ORDERED that:

- A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and perform all of its responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has

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not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.

- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
 - 1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
 - 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 - 3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and, with respect to

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each Divestiture Product that is a Contract Manufacture Product, until the earliest of: (i) the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and able to manufacture the Divestiture Product in final form in commercial quantities, in a manner consistent with cGMP, independently of the Respondent; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture such Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture that Divestiture Product;

provided, however, that, the Interim Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Orders.

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- F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
- G. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
- H. Respondent shall report to the Interim Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by each Acquirer with respect to the performance of Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days after the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Orders; *provided, however*, beginning ninety (90) days after Respondent has filed its final report pursuant to Paragraph VIII.C. of the Decision and Order, and ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by each Acquirer or

Order to Maintain Assets

the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in its final form in commercial quantities, in a manner consistent with cGMP, independent of Respondent.

- I. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The Interim Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

Order to Maintain Assets

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondent has fully complied with this Order to Maintain Assets and the Paragraphs that are enumerated in Paragraph VIII.C. of the related Decision and Order, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the Orders. Respondent shall submit at the same time a copy of its report concerning compliance with the Orders to the Interim Monitor, if any Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a detailed description of its efforts to comply with the relevant paragraphs of the Orders, including:

- A. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
- B. a detailed description of the timing for the completion of such obligations.

provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph VIII of the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of the Respondent;

Order to Maintain Assets

- B. any proposed acquisition, merger or consolidation of the Respondent; or
- C. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate as of:

- A. the later of the following dates:

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1. three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34;
 2. the day after the divestiture of all of the Divestiture Product Assets, as required by and described in the Decision and Order, has been completed; or
 3. the day after the Product Manufacturing Technology related to each Divestiture Product has been provided to the Acquirer in a manner consistent with the Technology Transfer Standards and the Interim Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to the provision of the Product Manufacturing Technology are complete;
- B. if the Acquisition does not occur, the Expiration Date; or
- C. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Mylan N.V. (“Respondent” or “Mylan”) of the voting securities of Perrigo Company plc (“Perrigo”), and Respondent having been furnished thereafter with a copy of a draft of

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Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations 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

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having modified the Decision and Order in certain respects, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

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:

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Corporate Secretary, 1000 Mylan Boulevard,
Canonsburg, Pennsylvania, 15317.

2. 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.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in the Order, the following definitions shall apply:

- A. “Mylan” or “Respondent” means: Mylan N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Mylan N.V. (including, without limitation, Mylan Pharmaceuticals Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include Perrigo.
- B. “Perrigo” means: Perrigo Company plc, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Perrigo Company plc, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.

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- D. “Acquirer(s)” means the following:
1. a Person specified by name in this Order to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
 2. a Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- E. “Acquisition” means Respondent’s acquisition of more than fifty percent (50%) of the voting securities of Perrigo.
- F. “Acquisition Date” means the date on which the Acquisition is consummated.
- G. “Acyclovir Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Mylan pursuant to the following Application: ANDA #202459, and any supplements, amendments, or revisions to this Application. This Product is a topically administered ointment containing, as an active pharmaceutical ingredient, acyclovir at a 5% strength.
- H. “Acyclovir Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Acyclovir Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Acyclovir Products.

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- I. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- J. “Alvogen” means Alvogen Group, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal executive offices located at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058, or any of Alvogen Group, Inc.’s wholly-owned subsidiaries.
- K. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. The term “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.
- L. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement, and sale of a Product.

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- M. “Bromocriptine Mesylate Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Mylan pursuant to the following Application: ANDA #076962, and any supplements, amendments, or revisions to this Application. This Product is an orally administered tablet containing, as an active pharmaceutical ingredient, bromocriptine mesylate at an Eq 2.5mg base strength.
- N. “Bromocriptine Mesylate Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Bromocriptine Mesylate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Bromocriptine Mesylate Products.
- O. “Categorized Assets” means the following assets and rights of Mylan, as such assets and rights are in existence as of the date Mylan signs the Agreement Containing Consent Orders in this matter and as are maintained by the Respondent in accordance with the Order to Maintain Assets until the Closing Date for each Divestiture Product:
1. all rights to all of the Applications related to the specified Divestiture Product;
 2. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
 3. all Product Approvals related to the specified Divestiture Product;
 4. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;

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5. all Product Marketing Materials related to the specified Divestiture Product;
6. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
7. all Website(s) related exclusively to the specified Divestiture Product;
8. the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;
9. for each specified Divestiture Product that has been marketed or sold by the Respondent prior to the Closing Date, a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
 - a. to require Respondent to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement or the Mylan Limited License;
 - b. to prohibit Respondent from seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law;
 - c. to seek to change any cross-referencing by a customer of those NDC Numbers with a

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Retained Product (including the right to receive notification from the Respondent of any such cross-referencing that is discovered by the Respondent);

- d. to seek cross-referencing from a customer of the Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
 - e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement or the Mylan Limited License; and
 - f. to approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondent prior to such notification(s) being disseminated to the customer(s);
- 10. all Product Development Reports related to the specified Divestiture Product;
 - 11. at the option of the Acquirer of the specified Divestiture Product, all Product Contracts related to the specified Divestiture Product;
 - 12. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the

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investigation of adverse effects related to the specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);

13. for each specified Divestiture Product that has been marketed or sold by the Respondent prior to the Closing Date,
 - a. a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;
 - b. for each month for each High Volume Account for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: the average net price per unit, *i.e.*, the final price per unit charged by Mylan net of all discounts, rebates, or promotions; the highest net price per unit; and the lowest net price per unit; and
 - c. for each month for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: the average wholesale price; wholesale acquisition cost; and price to Medicare;

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14. for each specified Divestiture Product, a list of all active pharmaceutical ingredient suppliers and all single-source excipient suppliers listed on any Application of a Retained Product that is the Therapeutic Equivalent of that Divestiture Product;
15. for each specified Divestiture Product that is a Contract Manufacture Product:
 - a. a list of the inventory levels (weeks of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler or distributor) as of the Closing Date; and
 - b. anticipated reorder dates for each customer as of the Closing Date;
16. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the specified Divestiture Product;
17. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
18. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and
19. all of the Respondent's books, records, and files directly related to the foregoing;

provided, however, that "Categorized Assets" shall not include the following: (i) documents relating to

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Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the specified Divestiture Product; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Interim Monitor or the Acquirer of the specified Divestiture Product; (iv) information that is exclusively related to the Retained Products; (v) any real estate and the buildings and other permanent structures located on such real estate; and (vi) all Product Licensed Intellectual Property;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Divestiture Product and to Retained Products or Businesses of the Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which the Respondent has a legal obligation to retain the original copies, the Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

- P. "cGMP" means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug,

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and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.

- Q. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- R. “Clindamycin Phosphate/Benzoyl Peroxide Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Mylan pursuant to the following Application: ANDA #065443, and any supplements, amendments, or revisions to this Application. This Product is a topically administered gel containing, as active pharmaceutical ingredients, benzoyl peroxide and clindamycin phosphate at a 5%; Eq 1% base strength.
- S. “Clindamycin Phosphate/Benzoyl Peroxide Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Clindamycin Phosphate/Benzoyl Peroxide Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Clindamycin Phosphate/Benzoyl Peroxide Products.
- T. “Closing Date” means, as to each Divestiture Product, the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- U. “Confidential Business Information” means all information owned by, or in the possession or control of, the Respondent that is not in the public domain and

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that is directly related to the conduct of the Business related to a Divestiture Product(s). The term “Confidential Business Information” *excludes* all of the following:

1. information relating to Respondent’s general business strategies or practices that does not discuss with particularity the Divestiture Products;
2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the specified Divestiture Product(s);
3. information that is contained in documents, records or books of the Respondent that is provided to an Acquirer by the Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and
4. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

V. “Contract Manufacture” means each of the following:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;
2. to manufacture, or to cause to be manufactured, a Product that is the Therapeutic Equivalent and in the identical dosage strength, formulation, and presentation as a Contract Manufacture Product on behalf of an Acquirer; or
3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a

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Contract Manufacture Product on behalf of an Acquirer.

W. “Contract Manufacture Product(s)” means the following, individually and collectively:

1. Acyclovir Products;
2. Bromocriptine Mesylate Products;
3. Clindamycin Phosphate/Benzoyl Peroxide Products;
4. Hydromorphone ER Products;
5. Liothyronine Sodium Products;
6. Polyethylene Glycol 3350 Products;
7. Scopolamine Products; and
8. any ingredient, material, or component used in the manufacture of the foregoing Products including the active pharmaceutical ingredient, excipients, or packaging materials (including, without limitation, drug vials);

provided however, that with the consent of the Acquirer of the specified Divestiture Product, the Respondent may substitute a Therapeutic Equivalent form of such Product in performance of the Respondent’s agreement to Contract Manufacture.

X. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining

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any and all approvals, licenses, registrations, or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and/or sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.

- Y. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of the Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee;

provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.

- Z. “Divestiture Agreements” means the following agreements:
1. *Asset Purchase Agreement* by and between Mylan N.V. and Alvogen Group, Inc., dated as of September 30, 2015;
 2. *Supply and Technology Transfer Agreement* by and between Mylan Pharmaceuticals Inc. and Alvogen Group, Inc., in the form submitted by the Respondent to the Commission prior to the Order Date, to be executed on the Closing Date; and
 3. all amendments, exhibits, agreements, and schedules attached to and submitted with the foregoing listed agreements;

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provided, however, the Mylan Limited License is not a Divestiture Agreement.

The Divestiture Agreements are contained in Non-Public Appendix I. Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

- AA. "Divestiture Product(s)" means the following, individually and collectively:
1. Acyclovir Products;
 2. Bromocriptine Mesylate Products;
 3. Clindamycin Phosphate/Benzoyl Peroxide Products;
 4. Hydromorphone ER Products;
 5. Liothyronine Sodium Products;
 6. Polyethylene Glycol 3350 Products; and
 7. Scopolamine Products.
- BB. "Divestiture Product Assets" means the following, individually and collectively:
1. Acyclovir Product Assets;
 2. Bromocriptine Mesylate Product Assets;
 3. Clindamycin Phosphate/Benzoyl Peroxide Product Assets;
 4. Hydromorphone ER Product Assets;
 5. Liothyronine Sodium Product Assets;

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6. Polyethylene Glycol 3350 Product Assets; and

7. Scopolamine Product Assets.

CC. “Divestiture Product Core Employees” means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product.

DD. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondent:

1. to research and Develop the specified Divestiture Product(s) for marketing, distribution or sale within the Geographic Territory;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Product(s) within the Geographic Territory;
3. to import or export the specified Divestiture Product(s) to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the specified Divestiture Products in the Geographic Territory; and
4. to have the specified Divestiture Product(s) made anywhere in the world for distribution or sale within, or import into the Geographic Territory;

provided however, that for any Product Licensed Intellectual Property or Product Manufacturing Technology that is the subject of a license from a Third Party entered into by the Respondent prior to the Acquisition, the scope of the rights granted hereunder

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shall only be required to be equal to the scope of the rights granted by the Third Party to the Respondent.

- EE. “Divestiture Product Releasee(s)” means any of the following Persons:
1. the Acquirer for the assets related to a particular Divestiture Product;
 2. any Person controlled by or under common control with that Acquirer; and
 3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.
- FF. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- GG. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- HH. “Drug Master File(s)” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- II. “Expiration Date” means the earliest of the following dates:
1. the date on which the Respondent withdraws its tender offer for the voting securities of Perrigo;

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2. the date on which Respondent's tender offer for the voting securities of Perrigo expires without extension or amendment by Respondent;
 3. the date on which a Person other than the Respondent acquires fifty (50) percent or more of the voting securities of Perrigo; or
 4. the date five (5) months after the Order Date.
- JJ. "Geographic Territory" shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.
- KK. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- LL. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States of America from the Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the Respondent's U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the specified Divestiture Product; or (iv) the end of the last quarter following the Acquisition or the Closing Date.
- MM. "Hydromorphone ER Product(s)" means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Mylan pursuant to the following Application: ANDA #206722; and any supplements, amendments, or

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revisions to this Application. These Products are extended release orally administered tablets containing, as an active pharmaceutical ingredient, hydromorphone hydrochloride, at the following strengths: 8mg, 12mg, 16mg, and 32mg.

- NN. “Hydromorphone ER Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Hydromorphone ER Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Hydromorphone ER Products.
- OO. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- PP. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- QQ. “Liothyronine Sodium Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Mylan pursuant to the following Application: ANDA #090326; and any supplements, amendments, or revisions to this Application. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, liothyronine sodium, at the following strengths: Eq 0.005mg base, Eq 0.025mg base, and Eq 0.05mg base.
- RR. “Liothyronine Sodium Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Liothyronine Sodium Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Liothyronine Sodium Products.

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- SS. “Manufacturing Designee” means any Person other than the Respondent or Perrigo that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- TT. “Mylan Limited License” means a non-exclusive and non-renewable license to Mylan to the Product Intellectual Property, the Product Manufacturing Technology, the Product Marketing Materials, the content that is displayed on any Website (to the extent any content is not in the public domain), and the Applications related to the Acyclovir Products: (i) to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Acyclovir Product(s) within the Geographic Territory; (ii) to import or export the Acyclovir Product(s) to or from the Geographic Territory to the extent related to the marketing, distribution, or sale of these Products in the Geographic Territory; and (iii) to use any Confidential Business Information related to the Acyclovir Products, but solely as is necessary to give effect to this license. The Mylan Limited License shall terminate on or before the earlier of the following dates:
1. the date thirty (30) days after the date on which Perrigo or Respondent receives final FDA approval to market a Product that is the Therapeutic Equivalent of the Acyclovir Products; or
 2. the date three (3) years after the Closing Date for the Acyclovir Products.
- The Mylan Limited License is contained in Non-Public Appendix I to this Order.
- UU. “NDC Number(s)” means the National Drug Code Number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.

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- VV. “Orders” means this Decision and Order and the related Order to Maintain Assets.
- WW. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- XX. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- YY. “Ownership Interest” means any and all rights, title, and interest, present or contingent to hold any of the following:
1. any voting or non-voting stock, share capital, equity, other interests, or beneficial ownership in a specified entity;
 2. any notes or options convertible into any voting or non-voting stock in a specified entity;
 3. assets that comprise fifty (50) percent or more of a specified entity; or
 4. assets that comprise fifty (50) percent or more of a subsidiary of a specified entity.
- ZZ. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.

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- AAA. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- BBB. “Polyethylene Glycol 3350 Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Respondent pursuant to the following Application: ANDA #078915; and any supplements, amendments, or revisions to this Application. These Products are orally administered powder (available packaged in either packets or in bulk containers) containing, as an active pharmaceutical ingredient, polyethylene glycol in the following strengths: 17gm/packet, and 17gm/scoopful.
- CCC. “Polyethylene Glycol 3350 Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Polyethylene Glycol 3350 Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Polyethylene Glycol 3350 Products.
- DDD. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- EEE. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product within the United States of America, and includes, without limitation, all approvals,

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registrations, licenses or authorizations granted in connection with any Application related to that Product.

FFF. “Product Contracts” means all of the following contracts or agreements:

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from the Respondent unless such contract applies generally to the applicable entity’s sales of Products to that Third Party;
2. pursuant to which the Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in connection with the manufacture of the specified Divestiture Product;
3. relating to any Clinical Trials involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture

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Product as a finished Product on behalf of the Respondent;

7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of the Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to the Respondent;
9. pursuant to which a Third Party is licensed by the Respondent to use the Product Manufacturing Technology;
10. constituting confidentiality agreements involving the specified Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the specified Divestiture Product to the Respondent including, but not limited to, consultation arrangements; and
13. pursuant to which any Third Party collaborates with Respondent in the performance of research, Development, marketing, distribution, or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), the Respondent shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such

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rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

GGG. “Product Copyrights” means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical, and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product’s sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of the Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto

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(including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

HHH. “Product Development Reports” means all of the following:

1. pharmacokinetic study reports related to the specified Divestiture Product;
2. bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA-approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;

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8. FDA-approved patient circulars and information related to the specified Divestiture Product;
9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components, and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;

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17. manufacturing batch records related to the specified Divestiture Product;
 18. stability testing records related to the specified Divestiture Product;
 19. change in control history related to the specified Divestiture Product; and
 20. executed validation and qualification protocols and reports related to the specified Divestiture Product.
- III. “Product Employee Information” means the following, for each Divestiture Product Core Employee, and as to the extent permitted by Law:
1. a complete and accurate list containing the name of each Divestiture Product Core Employee (including former employees who were employed by the Respondent within ninety (90) days of the execution date of any Remedial Agreement);
 2. with respect to each such employee, the following information:
 - a. the date of hire and effective service date;
 - b. job title or position held;
 - c. a specific description of the employee’s responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, the Respondent may provide the employee’s most recent performance appraisal;
 - d. the base salary or current wages;
 - e. the most recent bonus paid, aggregate annual compensation for the Respondent’s last fiscal

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year, and current target or guaranteed bonus, if any;

- f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
 - g. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

JJJ. "Product Intellectual Property" means all of the following intellectual property related to a Divestiture Product (other than Product Licensed Intellectual Property) that is owned, licensed or controlled by Respondent as of the Closing Date:

- 1. Patents;
- 2. Product Copyrights;
- 3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information; and
- 4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present, or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;

provided, however, that "Product Intellectual Property" does not include the corporate names or

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corporate trade dress of “Mylan” or “Perrigo” or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof, or general registered images or symbols by which Mylan, or Perrigo can be identified or defined.

KKK. “Product Licensed Intellectual Property” means the following:

1. all of the following intellectual property related to a Divestiture Product that is owned, licensed, or controlled by Mylan as of the Closing Date:
 - a. Patents that are related to a Divestiture Product that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date;
 - b. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product and that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and
2. in those instances in which the Respondent or Perrigo (i) is the holder of an NDA for a Product that is the Therapeutic Equivalent of any Divestiture Product that is the subject of an ANDA, (ii) the NDA is not subject to an exclusive license to a Third Party, and (iii) the Product

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subject to such NDA is a Retained Product, a full, complete and unlimited Right of Reference or Use to the Drug Master File related to the NDA for this Retained Product to reference or use in any Application related to that Divestiture Product.

LLL. “Product Manufacturing Employees” means all salaried employees of the Respondent who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the specified Divestiture Product (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

MMM. “Product Manufacturing Technology” means all of the following related to a Divestiture Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
2. all ingredients, materials, or components used in the manufacture of that Product including the

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active pharmaceutical ingredient, excipients or packaging materials; and

3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture that Product.

NNN. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Divestiture Product.

OOO. "Product Research and Development Employees" means all salaried employees of Respondent who have directly participated in the research, Development, regulatory approval process, or clinical studies of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

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- PPP. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information.
- QQQ. “Product Trade Dress” means the current trade dress of a Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.
- RRR. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.
- SSS. “Proposed Acquirer” means a Person proposed by the Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to this Order.
- TTT. “Remedial Agreement(s)” means the following:
1. any agreement between the Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;

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2. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
3. any agreement between the Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by the Respondent to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; or
4. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

UUU. "Retained Product" means any Product(s) other than a Divestiture Product.

VVV. "Right of Reference or Use" means, for the purpose of obtaining approval of an Application or to defend an

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Application, the authority to rely upon, and otherwise use, (i) an investigation of the quality, safety or efficacy of a Product (including any or all such investigations conducted *in vitro*, *in vivo*, or *in silico* and any and all Clinical Trials), (ii) Product Development Reports, or (iii) Product Scientific and Regulatory Material, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.

WWW. “Scopolamine Product(s)” means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Mylan pursuant to the following Application: ANDA #203753; and any supplements, amendments, or revisions to this Application. These Products are transdermally administered extended release films (patches) containing, as an active pharmaceutical ingredient, scopolamine at a strength of 1mg/72-hours.

XXX. “Scopolamine Product Assets” means all rights, title and interest in and to all assets related to the Business of Mylan within the Geographic Territory related to each of the Scopolamine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Scopolamine Products.

YYY. “Supply Cost” means a cost not to exceed the Respondent’s average direct per unit cost in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product,

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“Supply Cost” means the cost as specified in such Remedial Agreement for that Divestiture Product.

ZZZ. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,

1. designating employees of the Respondent knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and
4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:

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- a. manufacture the specified Divestiture Product in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Divestiture Product;
- b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
- c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

AAAA. “Therapeutic Equivalent” means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product.

BBBB. “Third Party(ies)” means any non-governmental Person other than the following: the Respondent; Perrigo; or the Acquirer of particular assets or rights pursuant to this Order.

CCCC. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that the Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

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II.

IT IS FURTHER ORDERED that, if the Acquisition occurs, all of the following provisions of Paragraph II of this Order shall apply:

DDDD. Not later than thirty (30) days after the Acquisition Date, Respondent shall divest the Divestiture Product Assets and grant the related Divestiture Product License, absolutely and in good faith, to Alvogen pursuant to, and in accordance with, the Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Alvogen or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Divestiture Product Assets, is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent has divested the Divestiture Product Assets to Alvogen prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that Alvogen is not an acceptable purchaser of the Divestiture Product Assets, then Respondent shall immediately rescind the transaction with Alvogen, in whole or in part, as directed by the Commission, and shall divest the Divestiture Product Assets not later than one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondent has divested the Divestiture Product Assets to Alvogen prior to the Order Date, and if, at the time the Commission determines to make this Order final and

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effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Divestiture Product Assets to Alvogen (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

EEEE. Prior to the Closing Date for each respective Divestiture Product, Respondent shall provide each Acquirer with the opportunity to review all contracts or agreements that are Product Contracts related to the Divestiture Products being acquired by that Acquirer for the purposes of the Acquirer determining whether to assume such contracts or agreements.

FFFF. Prior to the Closing Date for each respective Divestiture Product, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

provided, however, Respondent may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

GGGG. Respondent shall:

1. submit to each Acquirer, at Respondent's expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;

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2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
 - a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to the relevant Acquirer, provide that Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as permitted by this Order or as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondent's obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;

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5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except: (i) the Acquirer of the particular Divestiture Products; (ii) other Persons authorized by that Acquirer to receive such information (*e.g.*, employees of the Respondent responsible for the Contract Manufacture of a Divestiture Product on behalf the Acquirer); (iii) the Commission; (iv) the Interim Monitor (if any has been appointed); or (v) Persons necessary to give effect to the Mylan Limited License; and
6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products; *provided however*, that, with respect to the Acyclovir Products that are the subject of the Mylan Limited License, this provision shall only apply to the Confidential Business Information related to the ongoing marketing or sales of the Acyclovir Products by the Acquirer (*e.g.*, information on purchases made by the Acquirer under any agreement with the Respondent to Contract Manufacture) and shall not apply to historical Confidential Business Information (*i.e.*, such information as is generated prior to the Closing Date).

HHHH. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall provide, or cause to be provided to that Acquirer in a manner consistent with the Technology Transfer Standards the following:

1. all Product Manufacturing Technology (including all related intellectual property) related to the

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Divestiture Product(s) being acquired by that Acquirer; and

2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to the Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondent shall obtain any consents from Third Parties required to comply with this provision. Respondent shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondent shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to that Acquirer.

III. With respect to each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall:

1. upon reasonable written notice and request from an Acquirer to the Respondent, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products acquired by that Acquirer at Supply Cost, for a period of time sufficient to allow that

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Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondent and Perrigo, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Application(s) of the Respondent from Persons other than Respondent or Perrigo;

2. make representations and warranties to the Acquirer that the Contract Manufacture Product(s) supplied by the Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the Respondent shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by the Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving the Respondent prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further, however,* that this obligation shall not require Respondent to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that

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exceed the representations and warranties made by the Respondent to the Acquirer in an agreement to Contract Manufacture;

provided further, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on the Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement to meet cGMP;

3. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondent's own use or sale;
4. make representations and warranties to each Acquirer that Respondent shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s) unless Respondent can demonstrate that the failure was beyond the control of Respondent and in no part the result of negligence or willful misconduct by the Respondent;

provided, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on the Respondent's aggregate liability for such a failure;

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5. during the term of any agreement to Contract Manufacture, upon written request of that Acquirer or the Interim Monitor (if any has been appointed), make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;
6. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);
7. in the event Respondent becomes (i) unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer and (ii) that Product is the subject of an ANDA, then Respondent shall provide a Product that is the Therapeutic Equivalent of such Contract Manufacture Product from the facility(ies) that Respondent uses or has used to source its own supply of the Product that is a Therapeutic Equivalent of the Contract Manufacture Product where such facility(ies) is still suitable for use for such manufacturing;
8. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Interim Monitor to monitor compliance with the obligations to Contract Manufacture; and
9. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of the Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to

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obtain all Product Approvals to manufacture the Contract Manufacture Products acquired by that Acquirer in the same quality achieved by, or on behalf of, the Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products.

The foregoing provisions, II.F.1. - 9., shall remain in effect with respect to each Contract Manufacture Product until the earliest of the following dates: (i) the date the Acquirer (or the Manufacturing Designee(s) of that Acquirer) is approved by the FDA to manufacture and sell such Contract Manufacture Product in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (ii) the date the Acquirer notifies the Commission and Respondent of its intention to abandon its efforts to manufacture the relevant Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the relevant Contract Manufacture Product; or (iv) the date five (5) years after the Closing Date;

- JJJJ. Respondent shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of those Retained Products that are the Therapeutic Equivalent of the Divestiture Products, in each case who have or may have had access to

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Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order or as otherwise permitted by this Order).

KKKK. Not later than thirty (30) days after the Closing Date, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to the relevant Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondent shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

LLLL. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall:

1. for a period of twelve (12) months after the Closing Date or until the hiring of twenty (20) Divestiture Product Core Employees by that

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Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the “Divestiture Product Core Employee Access Period(s)”;

2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay;

provided, however, that the provision of such information may be conditioned upon the Acquirer’s or Proposed Acquirer’s written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, (iii) restrict access to the information to such of the Acquirer’s or Proposed Acquirer’s employees who need such access in connection with the specified and permitted use, and (iv) destroy or return the information without retaining copies at such time as the specified and permitted use ends;

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3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, Respondent shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondent from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee

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compensation and benefits offered by Respondent until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law); and,

5. for a period of one (1) year after the Closing Date, not, directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or hire any Divestiture Product Employee;

provided, however, Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with the Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that the Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts the Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondent;

provided further, however, that nothing in this Order shall be construed to require Respondent to terminate the employment of any employee or to prevent Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition.

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MMMM. Until Respondent completes the divestitures required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer,

1. Respondent shall take actions as are necessary to:
 - a. maintain the full economic viability and marketability of the Businesses associated with that Divestiture Product;
 - b. minimize any risk of loss of competitive potential for that Business;
 - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product except for ordinary wear and tear;
 - d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product; and
 - e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
2. Respondent shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses associated with that Divestiture Product.

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NNNN. Respondent shall not join, file, prosecute, or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer under any of the following:

1. any Patent owned by or licensed to the Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof; or
2. any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to the Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. Respondent shall also covenant to that Acquirer that as a condition of any assignment or license from the Respondent to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of

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marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. The provisions of this Paragraph do not apply to any Patent owned by, acquired by or licensed to or from the Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

OOOO. Upon reasonable written notice and request from an Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer.

PPPP. For any patent infringement suit filed prior to the Closing Date in which the Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that the Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the

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Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Products; or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of such Divestiture Product(s), the Respondent shall:

1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from the Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;
2. waive conflicts of interest, if any, to allow the Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and
3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work-product in the possession of the Respondent's outside counsel related to that Divestiture Product.

QQQQ. Respondent may enter into the Mylan Limited License with the relevant Acquirer, in the form as is approved by the Commission in connection with the Commission's determination to make the Order final and effective;

provided however, that Respondent shall not modify, amend, extend, or renew the Mylan Limited License without the prior approval of the Commission or enter into any subsequent agreement to license the rights that are the subject of the Mylan Limited License without the prior approval of the Commission;

provided further, however, that any payment or fee from the Respondent to the Acquirer under the Mylan Limited License shall not be based, in whole or in part,

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on the actual sales of the Acyclovir Products or the actual profits from these Products.

RRRR. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related Product Manufacturing Technology (for the Contract Manufacture Products) and the related obligations imposed on the Respondent by this Order is:

1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory;
2. to create a viable and effective competitor, that is independent of Respondent and Perrigo in the Business of each Divestiture Product within the Geographic Territory; and
3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

III.

IT IS FURTHER ORDERED that:

SSSS. At any time after the Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that the Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.

TTTT. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor

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within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.

UUUU. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

VVVV. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and, with respect to each Divestiture Product that is a Contract Manufacture Product, until the earliest of: (i) the

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date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and able to manufacture the Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture that Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Divestiture Product;

provided, however, that, the Interim Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

WWWW. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Orders.

XXXX. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have

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authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

YYYY. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

ZZZZ. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by each Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order; *provided, however*, beginning ninety (90) days after Respondent has filed its final report pursuant to Paragraph VIII.C., and ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in its final form in commercial quantities, in a

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manner consistent with cGMP, independent of Respondent.

AAAAA. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

BBBBB. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

CCCCC. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

DDDDD. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.

EEEEEE. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.

IT IS FURTHER ORDERED that:

FFFFF. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer,

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deliver or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

GGGGG. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

HHHHH. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the

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Divestiture Trustee to effect the divestiture required by this Order.

- IIII. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee.

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Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses

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incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

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9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

JJJJ. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

KKKKK. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.

LLLLL. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

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- A. To assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

provided, however, that the Respondent may disclose such information as necessary for the purposes set forth in this Paragraph V pursuant to an appropriate confidentiality order, agreement or arrangement;

provided further, however, that pursuant to this Paragraph V, the Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VI.

IT IS FURTHER ORDERED that:

- C. If Respondent does not acquire more than fifty (50) percent of the voting securities of Perrigo on or before the Expiration Date, then, not later than twelve (12) months after the Expiration Date, Respondent shall divest, absolutely and in good faith, all of its Ownership Interest in Perrigo in one or more of the following manners:

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1. on the New York Stock Exchange, or such other securities exchange(s) as the voting securities of Perrigo are registered to be traded on;
 2. to Perrigo, *provided however*, that if any part of the consideration received by Respondent from Perrigo is anything other than cash, then the manner of the transaction shall be subject to the prior approval of the Commission; or
 3. to an Acquirer or Acquirers that receive the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission.
- D. Pending the divestiture described in Paragraph VI.A., Respondent shall not, directly or indirectly, do any of the following:
1. acquire any additional Ownership Interest in Perrigo;
 2. exercise dominion or control over, or otherwise seek to influence, the management direction or supervision of the business of Perrigo including, but not limited to, any participation in the formulation, determination or direction of any business decisions of Perrigo;
 3. propose corporate action requiring the approval of Perrigo shareholders;
 4. nominate, or in any other way seek or obtain representation on the Board of Directors of Perrigo;
 5. have any of the Respondent's directors, officers, or employees serve simultaneously as an officer or director of Perrigo;
 6. exercise any voting rights attached to any Ownership Interest in Perrigo; *provided, however*,

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that in any matter to be voted on by the shareholders of Perrigo, Respondent shall cast votes related to Respondent's Ownership Interest in each class of Perrigo stock in an amount and manner proportional to the vote of all other votes cast by other Perrigo shareholders entitled to vote on such matter;

7. seek or obtain access to any confidential, proprietary, or other non-public information from Perrigo relating to the research, Development, manufacture, distribution, sale, and marketing of Perrigo's Products; *provided however*, this provision shall not be construed to prohibit the Respondent from:
 - a. seeking or obtaining discovery in any litigation or other proceeding to resolve a claim between the Respondent and Perrigo in accordance with the procedures of the forum before which the dispute is pending. With respect to any such discovery, the Respondent shall enter into a protective order to prevent any information from being used for any purpose other than providing legal representation or evidence as to the particular dispute and to prevent any information from being disclosed to any person(s) not necessary to the resolution of such dispute; or
 - b. seeking information from Perrigo as a part of normal due diligence for the purposes of negotiating a transaction with Perrigo; or
 8. take any action or omit to take any action in a manner that would be incompatible with the status of the Respondent as a passive investor in Perrigo.
- E. If Respondent does not acquire more than fifty (50) percent of the voting securities of Perrigo on or before the Expiration Date, then, for a period of three (3)

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years beginning on the Expiration Date, Respondent shall not, without the prior approval of the Commission, do any of the following:

1. acquire, directly or indirectly, any Ownership Interest in Perrigo; or
 2. consummate, directly or indirectly, any merger or other combination with Perrigo.
- F. The purpose of the requirements of Paragraph VI is to ensure that, if the Acquisition does not occur in a timely manner, the Respondent will not seek to exert, or exert influence upon the business operations of Perrigo.

VII.**IT IS FURTHER ORDERED** that:

- G. Any Remedial Agreement shall be deemed incorporated into this Order.
- H. Any failure by the Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- I. Respondent shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of Respondent's obligation to the Acquirer pursuant to this Order.
- J. For each Divestiture Product that is a Contract Manufacture Product, Respondent shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in

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commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of the Respondent and Perrigo all as soon as reasonably practicable.

- K. Respondent shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- L. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

VIII.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition Date, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within five (5) days of the Expiration Date, Respondent shall submit to the Commission a letter certifying the date on which the Expiration Date occurred.
- C. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with Paragraphs II.A., II.B., II.C., II.D.1.,

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II.D.2., II.D.3., II.E., II.F., II.G., II.H., II.I. and II.J., Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
 2. a detailed description of the timing for the completion of such obligations.
- D. One (1) year after the Order Date, annually for the next two years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

IX.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- E. any proposed dissolution of the Respondent;
- F. any proposed acquisition, merger or consolidation of the Respondent; or

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- G. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

X.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XI.

IT IS FURTHER ORDERED that this Order shall terminate on February 19, 2026.

By the Commission.

Analysis to Aid Public Comment

**NON-PUBLIC APPENDIX I
AGREEMENTS RELATED TO THE DIVESTITURES****[Redacted From the Public Record Version, But Incorporated
By Reference]****ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

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”).

Analysis to Aid Public Comment

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.

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

Analysis to Aid Public Comment

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

Analysis to Aid Public Comment

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.

Analysis to Aid Public Comment

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.

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.

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,

Analysis to Aid Public Comment

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

Analysis to Aid Public Comment

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.

Complaint

IN THE MATTER OF

**CARROT NEUROTECHNOLOGY, INC.,
ADAM GOLDBERG,
AND
AARON SEITZ**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4567; File No. 142 3132

Complaint, February 22, 2016 – Decision, February 22, 2016

This consent order addresses Carrot Neurotechnology, Inc.’s advertising for the Ulimeyes software application. The complaint alleges that the respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act by representing that Ulimeyes substantially improves users’ vision. The consent order prohibits any representation about the health benefits, performance, efficacy, safety, or side effects of any product or service, unless it is non-misleading and supported by competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

Participants

For the *Commission*: Edward Glennon and Karen Mandel.

For the *Respondents*: James Kaminski and Stuart Sorkin,
Hughes Bentzen, PLLC.

COMPLAINT

The Federal Trade Commission, having reason to believe that Carrot Neurotechnology, Inc., a corporation, and Adam Goldberg and Aaron Seitz, individually and as owners and officers of the corporation (collectively, “Respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Carrot Neurotechnology, Inc. (“Carrot”) is a California corporation with its principal office or place of