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

**COMMISSIONERS:** 

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

In the Matter of

MYLAN N.V., a company. **Docket C-**

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### 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 Complaint that the Bureau of Competition proposed to present to the 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, 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: 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.

- 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

- 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;
  - 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 crossreferencing 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 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 AundTw 2 ane(ng)]TJ 9.7()Tj Mfi(D)2(i)-

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;
- 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 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, 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 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);

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 Re Tw -22.7c[(R)-3(e)4 and r,gin approvoiailndvpprtihed uinct (incD rec1

- 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;
  - 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 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. "

- 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.
- 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. on

- 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-

- 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, 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 Producton 3Sf 3 04(1f 1-4(r12(e)4)4(e)4

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 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

- 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;
- 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

- 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 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 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 acti

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 specificallree /H2 <</MCID 0>>

VVV. "Right of Reference or Use" means, for the purpose of obtaining approval of an Application or to defend an 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 Rep12(e)ce o(ls)]Tn, the a1 Tw 3.3 0 Td [(),)mm ]/B1.97 -1.17 67- Tc [(t)o2S

- 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:
  - 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 thuch W

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 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 agr

- 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 ov4(i)ovidy mated to17.s

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

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

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provided, however, that the Respondent may reserve the right to control the defense

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 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;

th

G. Respondent shall require, as a condition of continued employment post

- H. 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.
- I. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall:
  - for a period of twelve (12) months after 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 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) tv 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

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 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 o-10(il2(ve)4(s)-1(ve)4(na)4(nt)-2(s)-1()4(t)-2()]TJ -0.004 Tc t6(s).00)2(ni)-2(t)-2(e0 sa)-6(c)-6(qt T

# III.

# **IT IS FURTHER ORDERED** that:

A. At any time after the Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor"

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

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 on materim Monitor, issue on

- B. 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.
- C. 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 Divestiture Trustee to effect the divestiture required by this Order.
- D. 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. 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;

- E. 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.
- F. 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.
- G. 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:

- 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:

- A. 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:
  - 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.
- B. 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*, 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.

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

- A. any proposed dissolution of the Respondent;
- 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 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 a-2(n)-10(g)10( or-11(e)4(nc]T]Tv-12(n 4(e)4(s)-1(, )-1(ha)4(l)-2(l)-2(, b4( )]TJ [(-1.17 TD [(a))3(e)-10(a))4(l)-2(l)-2(a) + 10(a) + 10

# NON-PUBLIC APPENDIX I AGREEMENTS RELATED TO THE DIVESTITURES

[Redacted From the Public Record Version, But Incorporated By Reference]