

Complaint

IN THE MATTER OF

PERRIGO COMPANY
AND
PADDOCK LABORATORIES, INC.

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-4329; File No. 111 0083

Complaint, July 22, 2011 – Decision, June 21, 2012

This consent order addresses the \$540 million acquisition by Perrigo Company of certain assets of Paddock Laboratories, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act by substantially lessening competition in the U.S. markets for the manufacture and sale of generic: (1) ammonium lactate cream; (2) ammonium lactate lotion; (3) ciclopirox shampoo; (4) promethazine suppository; (5) clobetasol spray; (6) diclofenac solution (collectively, the “Products”); and (7) testosterone gel. The consent order requires the companies to divest Paddock’s rights and assets necessary to manufacture and market generic: (1) ammonium lactate external cream 12 percent (“ammonium lactate cream”); (2) ammonium lactate topical lotion 12 percent (“ammonium lactate lotion”); (3) ciclopirox shampoo 1 percent (“ciclopirox shampoo”); and (4) promethazine hydrochloride rectal suppository 12.5 mg and 25 mg (“promethazine suppository”) to Watson Pharmaceuticals, Inc. The consent order also requires the companies to divest all of Perrigo’s rights and assets necessary to manufacture and market generic clobetasol propionate spray 0.05 percent (“clobetasol spray”) and diclofenac sodium topical solution 1.5 percent (“diclofenac solution”) to Watson.

Participants

For the *Commission*: Christine Palumbo, Susan Huber, and Aylin M. Skroejer.

For the *Respondents*: Scott A. Stempel, Morgan, Lewis & Bockius LLP; Garret G. Rasmussen, Orrick, Herrington & Sutcliffe LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade

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Commission (“Commission”), having reason to believe that Respondent Perrigo Company (“Perrigo”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire substantially all of the assets of Paddock Laboratories, Inc. (“Paddock”), a corporation subject to the jurisdiction of the Commission, in violation 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 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. DEFINITIONS

1. “Commission” means the Federal Trade Commission.
2. “FDA” means the United States Food and Drug Administration.
3. “Respondents” means Perrigo and Paddock, individually and collectively.

II. RESPONDENTS

4. Respondent Perrigo is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Michigan, with its headquarters address at 515 Eastern Avenue, Allegan, Michigan. Perrigo is engaged in the research, development, manufacture, and sale of generic pharmaceuticals.
5. Respondent Paddock is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Minnesota, with its headquarters address at 3940 Quebec Avenue North, Minneapolis, Minnesota. Paddock is engaged in the research, development, manufacture, and sale of generic pharmaceuticals.
6. Respondents are, and at all times relevant herein have been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and are corporations whose businesses are in or affect commerce, as

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“commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III. PROPOSED ACQUISITION

7. On January 20, 2011, Perrigo and Paddock entered into a Purchase Agreement whereby Perrigo proposes to acquire substantially all of the assets of Paddock in a transaction valued at approximately \$540 million (the “Acquisition”).

IV. RELEVANT MARKETS

8. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the manufacture and sale of the following generic pharmaceuticals:

- a. ammonium lactate external cream 12 percent (“ammonium lactate cream”);
- b. ammonium lactate topical lotion 12 percent (“ammonium lactate lotion”);
- c. ciclopirox shampoo 1 percent (“ciclopirox shampoo”);
- d. promethazine hydrochloride rectal suppository 12.5 mg and 25 mg (“promethazine suppository”);
- e. clobetasol propionate spray 0.05 percent (“clobetasol spray”);
- f. diclofenac sodium topical solution 1.5 percent (“diclofenac solution”); and
- g. testosterone gel 1 percent (“testosterone gel”).

9. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

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V. STRUCTURE OF THE MARKETS

10. The ammonium lactate cream and lotion products are prescription moisturizers used to treat dry, scaly skin conditions, and help relieve itching. The same firms compete in both markets – Perrigo, Paddock, and Taro Pharmaceutical Industries Ltd. (“Taro”), although Paddock has temporarily withdrawn its products from the U.S. market. Perrigo is the leading supplier in the U.S. market for ammonium lactate cream, with 70 percent of the market. In this market, the Acquisition would create a duopoly, with Perrigo accounting for approximately 87 percent. The Herfindahl-Hirschman Index (“HHI”) would increase by 2,380 points, resulting in a post-acquisition HHI of 7,714 points. Perrigo and Paddock are the leading suppliers of ammonium lactate lotion in the United States, with 43 percent and 50 percent of the market, respectively. The Acquisition would increase Perrigo’s market share to 93 percent and increase the HHI concentration by 4,300 points to 8,678 points.

11. Paddock leads the market for ciclopirox shampoo in the United States, with a share of 83 percent. Ciclopirox shampoo is a prescription shampoo used to treat seborrheic dermatitis, an inflammatory condition that causes flaky scales and patches on the scalp. Perrigo and E. Fougera & Co. are the only other U.S. suppliers of ciclopirox shampoo. After the Acquisition, Perrigo would control 99 percent of the market, and the HHI concentration would increase by 2,656 points to a post-acquisition HHI of 9,802 points.

12. The market for the manufacture and sale of promethazine suppository is also highly concentrated; Perrigo, Paddock, and G&W Laboratories, Inc. are currently the only U.S. suppliers. Promethazine suppository is indicated for a variety of uses, including to treat allergic reactions, to prevent and control motion sickness, and to relieve nausea and vomiting associated with surgery. The Acquisition would create a duopoly and increase Perrigo’s market share to 34 percent in the 12.5 mg strength, and to 35 percent in the 25 mg strength. The HHI would increase by 570 and 600 for the 12.5 mg and 25 mg strengths, resulting in post-acquisition HHIs of 5,512 and 5,450, respectively.

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13. Clobetasol spray is a topical steroid used to treat moderate to severe psoriasis in adults. Perrigo and Paddock are developing clobetasol sprays and are two of a limited number of suppliers capable of entering this future market in a timely manner.

14. Diclofenac solution is a non-steroidal anti-inflammatory drug used to treat osteoarthritis of the knee. Perrigo and Paddock are in the process of entering the diclofenac solution market and are two of a limited number of suppliers capable of entering this future market in a timely manner.

15. Testosterone gel is a prescription gel used to treat adult males who have a deficiency or absence of testosterone. Abbott Laboratories (“Abbott”) currently markets testosterone gel under the Androgel brand name. Perrigo is one of a limited number of suppliers capable of entering this future market in a timely manner. Par Pharmaceutical Companies, Inc. has an agreement with Abbott relating to AndroGel that provides for Abbott to make substantial annual payments to Paddock. The proposed acquisition would make Perrigo a party to that agreement, thereby enhancing Abbott’s and Perrigo’s ability to coordinate on delaying the introduction of Perrigo’s product into the market.

VI. ENTRY CONDITIONS

16. Entry into each of the relevant markets described in Paragraph 8 would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and FDA approval requirements take a minimum of two years. Moreover, entry is not likely because the relevant markets are relatively small, limiting sales opportunities for any new potential entrant.

VII. EFFECTS OF THE ACQUISITION

17. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets 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:

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- a. by eliminating actual, direct, and substantial competition between Perrigo and Paddock in the markets for ammonium lactate cream, ammonium lactate lotion, ciclopirox shampoo, and promethazine suppository, thereby: (1) increasing the likelihood that Perrigo will be able to unilaterally exercise market power; (2) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (3) increasing the likelihood that customers would be forced to pay higher prices;
- b. by eliminating future competition between Perrigo and Paddock in the markets for clobetasol spray and diclofenac solution, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of Perrigo's or Paddock's products in the markets; and (2) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from Perrigo's and Paddock's independent entry into the markets; and
- c. by (1) increasing the likelihood and degree of coordinated interaction between Perrigo and Abbott in the market for testosterone gel; (2) increasing the likelihood that the combined entity would forego or delay the launch of Perrigo's product in the testosterone gel market; and (3) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from Perrigo's independent entry into the testosterone gel market.

VIII. VIOLATIONS CHARGED

18. The Acquisition described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

19. The Acquisition described in Paragraph 7, if consummated, would constitute a violation of Section 7 of the

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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 twenty-second day of July, 2011, issues its Complaint against said Respondents.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Perrigo Company of substantially all of the assets and substantially all of the liabilities of Respondent Paddock Laboratories, Inc. (collectively “Respondents”), and Respondents 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 Respondents 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

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing: an admission by Respondents 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 Respondents 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 Respondents

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have violated the said Acts, and that a Complaint should issue stating its charges in that respect, 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 Perrigo Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of Michigan with its headquarters located at 515 Eastern Avenue, Allegan, Michigan 49010.
2. Respondent Paddock Laboratories, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Minnesota with its headquarters located at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, 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, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Perrigo” means Perrigo Company, 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, and the

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

- B. “Paddock” means Paddock Laboratories, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Paddock , Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” mean Perrigo and Paddock, collectively and individually.
- D. “Watson” means Watson Pharmaceuticals, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its headquarters address at 311 Bonnie Circle, Corona, California 92880.
- E. “Commission” means the Federal Trade Commission.
- F. “Acquirer(s)” means Watson or any other Person approved by the Commission to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to the Decision and Order.
- G. “Acquisition” means the acquisition contemplated by the Purchase Agreement by and among Perrigo Company, Paddock Laboratories, Inc., Paddock Properties Limited Partnership and, solely for purposes of Section 11.15, the person set forth on Exhibit A, Dated as of January 20, 2011.
- H. “Acquisition Date” means the date the Respondents close on the Acquisition.
- I. “Closing Date” means the date on which Respondents (or a Divestiture Trustee) consummate a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Products Assets and

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the Divestiture Products License to an Acquirer(s) pursuant to this Order.

- J. “Confidential Business Information” means information owned by, or in the possession or control of, Respondents that is not in the public domain.
- K. “Decision and Order” means the Decision and Order incorporated into and made a part of the Agreement Containing Consent Orders.
- L. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- M. “Monitor” means any monitor appointed pursuant to this Order or the related Decision and Order.
- N. “Orders” means this Order to Maintain Assets and the Decision and Order.
- O. “Proposed Acquirer” means Watson or any Person proposed by Respondents (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the Acquirer.

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

- A. Until Respondents complete the divestitures required by the Decision and Order, including transferring the Divestiture Products Assets and granting the Divestiture Products License(s), Respondents:
 - 1. Shall take such actions as are necessary to:
 - a. maintain the full economic viability and marketability of the Divestiture Products Businesses;

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- b. minimize any risk of loss of competitive potential of the Divestiture Products Businesses;
 - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Divestiture Products Businesses;
 - d. ensure the Divestiture Products Assets are provided to the Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to any Divestiture Product;
 - e. ensure the completeness of the transfer and delivery of the Divestiture Products Manufacturing Technology; and
2. shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in the Orders) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Divestiture Products Businesses,

provided that these obligations shall cease as to any particular Divestiture Product when Respondents have transferred to the Acquirer all assets and materials related to such product and have no further obligations regarding such product under any Contract Manufacturing Agreement.

B. Respondents shall:

- 1. not directly or indirectly use any Confidential Business Information related exclusively to one or more Divestiture Products other than as necessary to comply with the requirements of this Order, Respondents' obligations to the Acquirer under the terms of any Remedial Agreement, or applicable Law;

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2. not directly or indirectly disclose or convey any Confidential Business Information related exclusively to one or more Divestiture Products to any Person except the Acquirer or other Persons specifically authorized by the Acquirer to receive such information; and
 3. maintain the confidentiality of any Confidential Business Information related to one or more Divestiture Products with the same degree of care and protection as used to protect the Confidential Business Information of Respondents.
- C. The purpose of this Order is to maintain the full economic viability, marketability and competitiveness of the Divestiture Products Businesses through the full transfer and delivery of the Divestiture Products Assets and the Divestiture Products License to an Acquirer, to minimize any risk of loss of competitive potential for the Divestiture Products Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of any assets included in the Divestiture Products Assets or Divestiture Products Licenses, except for ordinary wear and tear.

III.**IT IS FURTHER ORDERED** that

- A. Until the Closing Date, Respondents shall provide all Divestiture Product Employees with reasonable financial incentives to continue in their positions and to continue the Divestiture Products Businesses in a manner consistent with past practices and/or as may be necessary to preserve the existing marketability, viability and competitiveness of the Divestiture Products and to ensure successful execution of the pre-Acquisition plans for such Divestiture Products. Such incentives shall include a continuation of all employee benefits offer by Respondents until the Closing Date, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by Law), and

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additional incentives as may be necessary to prevent any diminution of the competitiveness of the Divestiture Products.

- B. Until Respondent Perrigo fully transfers and delivers to the Acquirer the Divestiture Products Assets and grants the Divestiture Products License, Respondent Perrigo shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated with the Divestiture Products for the relevant Divestiture Products' last fiscal year
- C. For a period lasting until six (6) months after the Closing Date, each Respondent shall
 - 1. not later than ten (10) days after written request by the Acquirer or Proposed Acquirer, or staff of the Commission, provide, to the extent permitted by Law, the Acquirer with the following information with respect to Persons employed by such Respondent:
 - a. a complete and accurate list containing the name of each Divestiture Product Employee (including former employees who were employed by Respondents within ninety (90) days of the execution date of any Remedial Agreement); and
 - b. with respect to each such employee,
 - i. the date of hire and effective service date;
 - ii. job title or position held; and
 - iii. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, Respondents may provide the employee's most recent performance appraisal.

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2. not interfere with the hiring or employing by the Acquirer or its Manufacturing Designee of any Divestiture Products Employees or make any counteroffer to a Divestiture Products Employee who has received a written offer of employment from an Acquirer or its Manufacturing Designee; and remove any impediments within the control of the Respondent that may deter a Divestiture Products Employee from accepting employment with an Acquirer or its Manufacturing Designee, including, but not limited to, removing non-competition or non-disclosure provisions of employment or other contracts with a Respondent that may affect the ability or incentive of a Divestiture Products Employee to be employed by an Acquirer or its Manufacturing Designee.
 3. if requested by a Divestiture Products Employee, provide such employee with any requested records concerning his or her salary and benefits, including but not limited to, his or her base salary or current wages; his or her most recent bonus paid, aggregate annual compensation for the relevant Respondents' last fiscal year and current target or guaranteed bonus (if any); any material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and copies of all employee benefit plans and summary plan descriptions (if any) applicable to such employee.
- D. For a period lasting until one (1) year after Closing Date, Respondents shall not:
1. 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 (ACovered Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or

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2. hire such Covered Employee;

provided, however, Respondents may hire any former Covered Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with Respondents, as long as such employee was not solicited in violation of the terms of the Order; and

provided further, that Respondents may advertise for employees in newspapers, trade publications or other media not targeted specifically at Covered Employees; or hire a Covered Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from Respondents.

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

- A. The Commission may appoint a monitor or monitors (“Monitor”) to assure that Respondents expeditiously comply with all obligations and perform all responsibilities required by the Orders and the Remedial Agreements.
- B. The Commission appoints F. William Rahe as Monitor and approves the Monitor Agreement between F. William Rahe and Respondents, attached as Appendix A.
- C. The Monitor’s duties and responsibilities shall include the following:
 - 1. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
 - 2. The Monitor shall have the power and authority to monitor Respondents’ compliance with the Orders, and shall exercise such power and authority and

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carry out his or her duties and responsibilities in a manner consistent with the purposes of the Orders and in consultation with the Commission or its staff;

3. The Monitor shall, in his or her sole discretion, consult with Third Parties in the exercise of his or her duties under the Orders or any agreement between the Monitor and Respondents; and
 4. The Monitor shall evaluate the reports submitted to the Commission by Respondents pursuant to the Orders and the Consent Agreement, and within thirty (30) days from the date the Monitor receives a report, report in writing to the Commission concerning performance by Respondents of its obligations under the Orders.
- D. Respondents shall grant and transfer to the Monitor, and such Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities, including but not limited to the following:
1. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with the Orders;
 2. Subject to any demonstrated legally recognized privilege, Respondents shall provide the Monitor full and complete access to personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with the Orders;
 3. Respondents shall deliver to the Monitor a copy of each report submitted to the Commission pursuant to the Orders or the Consent Agreement;

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4. The Monitor shall serve, without bond or other security, at the expense of Respondent Perrigo, on such reasonable and customary terms and conditions to which the Monitor and Perrigo agree and that the Commission approves;
5. The Monitor shall have authority to use the services of or employ, at the expense of Respondent Perrigo, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
6. Respondents shall indemnify the Monitor and hold the Monitor harmless to the extent set forth in the Monitor Agreement executed on May 13, 2011; and
7. Respondents may require the Monitor and each of the 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 Monitor from providing any information to the Commission or require the Monitor to report to Respondents the substance of communications to or from the Commission or the Acquirer.

- E. The Commission may, among other things, require the Monitor and each of the 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 Monitor's duties.
- F. The Monitor shall serve until Respondents fully and finally transferred Divestiture Products Assets, granted the Divestiture Products License, and fulfilled all obligations under this Order to provide assistance, and

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manufacture and supply the Contract Manufacture Products.

- G. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed substitute Monitor, Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor.
- H. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- I. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

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

- A. Before the Closing Date, Respondents shall submit to staff of the Commission a verified written report setting forth in detail the procedures Respondents have implemented to:
 - 1. reasonably ensure that all employees and representatives who have or may be exposed to Confidential Business Information understand and are required to comply with the confidentiality obligations contained in Paragraph II.B of this Order and Paragraph II.I of the Decision and Order; and

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2. reasonably ensure that all employees and representatives of Respondents, including those hired during the term of the Order, understand and are required to comply with all terms of this Order that are relevant to their job duties.

In further compliance with this provision, Respondents shall provide staff of the Commission with written notice of all changes, additions and modifications to the procedures implemented, and shall include specific information detailing their efforts to comply with this paragraph in all reports of compliance required by this Order.

provided, however, that Respondent Paddock shall have no further obligations under this paragraph after the Acquisition Date.

- B. Respondents shall submit to the Commission and to the Monitor, 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, within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until the Decision and Order becomes final, and shall submit at the same time a copy of the report to the Monitor.

Respondents shall include in their compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with the Orders, including a full description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all Persons contacted, and shall make available to the Commission and the Monitor all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.

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provided, however, that Respondent Paddock shall have no further obligations under this paragraph after the Acquisition Date.

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

- A. Each Remedial Agreement shall be incorporated by reference into this Order to Maintain Assets, and made a part hereof. Further, nothing in any Remedial Agreement shall limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of an Acquirer or to reduce any obligations of Respondents under a Remedial Agreement. Respondents shall comply with the terms of each Remedial Agreement, and a breach by Respondents of any term of a Remedial Agreement shall constitute a violation of the Orders. To the extent that any term of a Remedial Agreement conflicts with a term of the Orders such that Respondents cannot fully comply with both, Respondents shall comply with the Orders.
- B. Respondents shall include in each Remedial Agreement a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of Respondents' obligations to the Acquirer pursuant to the Orders.
- C. Prior to the Closing Date, Respondents shall not modify or amend any material term of any Remedial Agreement without the prior approval of the Commission. Further, any failure to meet any material condition precedent to closing contained in any Remedial Agreement (whether waived or not) shall constitute a violation of the Orders.
- D. After the Closing Date and during the term of each Remedial Agreement, Respondents shall provide written notice to the Commission not more than five

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(5) days after any modification (material or otherwise) of the Remedial Agreement. Further, Respondents shall seek Commission approval of such modification (material or otherwise) within ten (10) days of filing such notification. If the Commission denies approval, the Commission will notify Respondents and Respondents shall expeditiously rescind the modification or make such other changes as are required by the Commission.

- E. Respondents 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 the Orders or the remedial purposes thereof.

VII.**IT IS FURTHER ORDERED** that

- A. 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 any Respondents made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, such Respondents shall, without restraint or interference, permit any duly authorized representative of the Commission:
 - 1. access, during business office hours of such Respondents 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 such Respondents related to compliance with this Order, which copying services shall be provided by such Respondents at the request of the authorized representative(s) of

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the Commission and at the expense of such Respondents; and

2. to interview officers, directors, or employees of such Respondents, who may have counsel present, regarding such matters.

VIII.

IT IS FURTHER ORDERED that this Order shall terminate

- A. 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; or
- B. The day after the day the related Decision and Order becomes final and effective.

By the Commission.

DECISION AND ORDER
[Redacted Public Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Perrigo Company of substantially all of the assets and substantially all of the liabilities of Respondent Paddock Laboratories, Inc. (collectively “Respondents”), and Respondents 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 Respondents 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

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Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing: an admission by Respondents 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 Respondents 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 Respondents have 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 Perrigo Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of Michigan with its headquarters located at 515 Eastern Avenue, Allegan, Michigan 49010.
2. Respondent Paddock Laboratories, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Minnesota with its headquarters located at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

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ORDER**I.**

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

- A. “Perrigo” means Perrigo Company, 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, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Paddock” means Paddock Laboratories, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Paddock Laboratories, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” mean Perrigo and Paddock, collectively and individually.
- D. “Watson” means Watson Pharmaceuticals, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its headquarters address at 311 Bonnie Circle, Corona, California 92880.
- E. “Commission” means the Federal Trade Commission.
- F. “Acquirer(s)” means Watson or any other Person approved by the Commission to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- G. “Acquisition” means the acquisition contemplated by the Purchase Agreement by and among Perrigo

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Company, Paddock Laboratories, Inc., Paddock Properties Limited Partnership and, solely for purposes of Section 11.15, the person set forth on Exhibit A, Dated as of January 20, 2011.

- H. “Acquisition Date” means the date the Respondents close on the Acquisition.
- I. “ANDA” means an abbreviated new drug application filed with the United States Food and Drug Administration (“FDA”), together with all revisions, supplements and amendments thereto.
- J. “Androgel Backup Supply Agreement” means the Backup Manufacturing and Supply Agreement, dated September 13, 2006, between Unimed Pharmaceuticals, Inc. and its Affiliates, Laboratoires Besins International S.A. and its Affiliates, and Par Pharmaceutical Companies, Inc. and its Affiliate, Par Pharmaceutical, Inc, including all amendments, exhibits, attachments, agreements, and schedules thereto, including, without limitation, the letter dated September 13, 2006, from Par Pharmaceutical Companies, Inc. to Paddock wherein Par designates Paddock as its Designee.
- K. “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.
- L. “Closing Date” means the date on which Respondents (or a Divestiture Trustee) consummate a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Products Assets and the Divestiture Products License to an Acquirer(s) pursuant to this Order.
- M. “Confidential Business Information” means information owned by, or in the possession or control of, Respondents that is not in the public domain.

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- N. “Contract Manufacture Agreement” means an agreement between Respondents and the Acquirer that has received prior approval of the Commission and by which Respondents shall manufacture or supply the Contract Manufactured Products to the Acquirer.
- O. “Contract Manufactured Products” means the Products manufactured, marketed or sold by Respondents pursuant to the following Product Approvals:
1. ANDA No. A090490 (generic shampoo with the active ingredient ciclopirox at a dosage strength of 1%);
 2. ANDA No. A040479 (generic rectal suppositories with the active ingredient promethazine hydrochloride in dosage strengths of 12.5 and 25 mg); and
 3. ANDA No. A075774 (generic external cream with the active ingredient ammonium lactate at a dosage strength of 12%); and
 4. ANDA No. A075570 (generic topical lotion with the active ingredient ammonium lactate at a dosage strength of 12%).
- P. “Direct Cost” means, with respect to a particular good or service Respondents are required to provide under the terms of this Order, i) the cost reflected or provided in a Remedial Agreement for the relevant good or service or, ii) if no cost is reflected or provided in a Remedial Agreement, the cost of labor, material, travel and other expenditures directly incurred to provide the relevant good or service. As used herein, the cost of labor for the use of the labor of an employee of Respondents shall not exceed the average hourly wage rate for such employee.
- Q. “Divestiture Products” means the Paddock Divestiture Products and the Perrigo ANDA Products.

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- R. “Divestiture Products Assets” means all of the Respondents’ rights, title and interest in all assets related to the Divestiture Products Businesses, to the extent legally transferable, including, without limitation, the following:
1. Product Applications related to one or more Divestiture Products and all Rights of Reference or Use to Drug Master Files related to such Product Applications;
 2. Product Approvals used in the Divestiture Products Businesses;
 3. Divestiture Products Marketing and Business Records;
 4. Divestiture Products Intellectual Property;
 5. Divestiture Products Manufacturing Technology;
 6. Divestiture Products Scientific and Regulatory Material;
 7. NDC Numbers used in the marketing and sale of a Divestiture Product (excluding the manufacturer’s FDA Labeler Code);
 8. At the Acquirer’s option, equipment used to manufacture one or more Divestiture Products to the extent such equipment is not readily available from a Third Party;
 9. At the Acquirer’s option, Divestiture Products Assumed Contracts, *provided, however*, that where a Divestiture Products Assumed Contract also relates to a Retained Product(s), Respondents shall assign the Acquirer all rights under the contract or agreement as are related to one or more Divestiture Products, but concurrently may retain similar rights for purposes related to any Retained Product(s); and

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10. To the extent included in a Remedial Agreement:

- a. 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 any Divestiture Product;
- b. unfilled customer purchase orders (subject to any rights of the customer);

provided, however, that “Divestiture Products Assets” shall not include any real estate or the buildings or other permanent structures located on such real estate; or assets used, as of the Acquisition Date, in the Research and Development, manufacture, distribution, sale or marketing of one or more Retained Products.

S. “Divestiture Products Assumed Contracts” means:

1. All contracts or agreements pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, one or more Divestiture Products from Respondents (unless such contract applies generally to such Respondents’ sales of Products to that Third Party);
2. All contracts or agreements pursuant to which Respondents 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 one or more Divestiture Products;
3. All contracts or agreements pursuant to which any Third Party provides any services used in the Research and Development, submitting Product Applications or obtaining Product Approvals for any Divestiture Product; and

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4. All contracts or agreements transferred, in whole or part, to an Acquirer pursuant to a Remedial Agreement.
- T. “Divestiture Products Businesses” means the Research and Development, manufacture, distribution, marketing and/or sale of the Paddock Divestiture Products and the Perrigo ANDA Products by Respondents.
- U. “Divestiture Products Employee(s)” means salaried employees of Respondents whose duties during the eighteen (18) month period immediately prior to the Closing Date, have related to the following (irrespective of the portion of working time involved and excluding employees whose participation consisted solely of oversight of legal, accounting, tax or financial compliance):
1. Research and Development of one or more Divestiture Products;
 2. The regulatory approval process for one or more Divestiture Products, including submitting Product Applications and obtaining and maintaining Product Approvals; or
 3. Manufacturing one or more Divestiture Products, including planning, design, implementation or operational management of Divestiture Products Manufacturing Technology.
- V. “Divestiture Products Intellectual Property” means all intellectual property owned or used by Respondents relating to one or more Divestiture Products, including Patents, copyrights (including the rights to all original works of authorship of any kind directly relating to the Divestiture Products or the Divestiture Products Businesses and any registration and applications for registrations thereof), Product Trademarks, product trade dress (including the current trade dress of each Divestiture Product including without limitation,

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Product packaging, and the lettering of the Product trade name), trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, Research and Development and other information and rights to obtain and file for patents and copyrights and registrations thereof;

provided, however, “Divestiture Products Intellectual Property” does not include the corporate names, copyrights or trade dress of “Perrigo” or “Paddock”, or any other corporations or companies owned or controlled by Respondents or the related logos thereof.

- W. “Divestiture Products License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to all Divestiture Products Intellectual Property, Divestiture Products Manufacturing Technology and Divestiture Products Marketing and Business Records not included in the Divestiture Products Assets,

provided however, that information relating solely to Retained Products shall be included in the Divestiture Products License solely to the extent such information cannot be segregated from information relating to one or more Divestiture Products in a manner that preserves the usefulness of the information relating to the Divestiture Products.

- X. “Divestiture Products Manufacturing Technology” means all technology, trade secrets, know-how, and proprietary data and information (whether patented, patentable or otherwise) related to the manufacture of one or more Divestiture Products including, but not limited to, the following: all product specifications, processes, 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

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communications and filings or submissions, trending and other metric reports, control history, manufacturing batch records, current and historical information associated cGMP compliance, and labeling and all other information related to the manufacturing process, supplier lists, and other master documents necessary for the manufacture, control and release of a Divestiture Product that is owned or controlled by Respondents or which Respondents have the right to receive.

- Y. “Divestiture Products Marketing and Business Records” means all records, documents, books, files and other information in whatever format stored or used that are related to the Divestiture Products Businesses, including without limitation:
1. All marketing materials used specifically in the marketing or sale of one or more Divestiture Products 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 one or more Divestiture Products; *excluding however*, the pricing of any Divestiture Products to customers;
 2. Website(s) related exclusively to one or more Divestiture Products, including the domain names

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(universal resource locators) and registration(s) thereof issued by any Person or authority that issues and maintains domain name registration for such websites, and copyrights to, and electronic files containing, all content available to or through such websites, *excluding, however*, (i) content not owned by Respondents for which Respondents cannot transfer rights to the Acquirer, (ii) trademarks and service marks other than the Product Trademarks required to be divested; and (iii) content not directly related to one or more Divestiture Products. The electronic files containing the relevant content shall be delivered in a format acceptable to the Acquirer; and

3. Copies of all unfilled customer purchase orders as of the Closing Date,

provided, however, that Divestiture Products Marketing and Business Records shall not include (1) documents relating to Respondents' general business strategies or practices, where such documents do not discuss with particularity any Divestiture Product; (2) administrative, financial, and accounting records; or (3) quality control records that are determined by the Monitor or the Acquirer not to be material to the manufacture of any Divestiture Product.

- Z. "Divestiture Products Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and clinical trial materials and information related to one or more Divestiture Products that are owned and controlled by Respondents or which Respondents have a right to receive including, but not limited to:

1. Study reports related to one or more Divestiture Products, including pharmacokinetic study reports, bioavailability study reports (including reference listed drug information), and bioequivalence study reports (including reference listed drug information);

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2. All communications with the FDA related to one or more Divestiture Products, including correspondence to Respondent(s) from the FDA and all filings, submissions and correspondence from a Respondent to the FDA relating to any Divestiture Product;
3. Annual and periodic reports related to any ANDA used in the Divestiture Products Businesses, including but not limited to, any safety update reports;
4. Product labeling, inserts and other information related to one or more Divestiture Products, including but not limited to,
 - a. FDA approved Product labeling,
 - b. currently used product package inserts (including historical change of control summaries),
 - c. FDA approved patient circulars and information related to one or more Divestiture Products;
5. Product recall reports filed with the FDA related to one or more Divestiture Products, and all reports, studies and other documents related to such recalls;
6. Adverse events/serious adverse event summaries related to one or more Divestiture Products;
7. Summaries of Product complaints
 - a. from physicians related to one or more Divestiture Products, and
 - b. from customers related to one or more Divestiture Products;

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8. Deviation reports, investigation reports and other investigational documents relating to one or more Divestiture Products, including but not limited to,
 - a. Out Of Specification (OOS) and Out Of Trend (OOT) reports,
 - b. Quality Control Data,
 - c. Field Alerts,
 - d. Change control history,
 - e. Information and data trending information, and
 - f. Rejects;
 9. Validation and qualification data and information, including but not limited to studies, protocols and reports;
 10. Reports, documents and information from all consultants or outside contractors engaged to investigate or perform special testing for the purpose of resolving product or process issues such as identification and sources of impurities;
 11. Reports of vendors of active pharmaceutical ingredients (“APIs”), excipients, packaging components and detergents as to specifications, degradation, chemical interactions, testing and historical trends; and
 12. Analytical methods development records.
- AA. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- BB. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

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- CC. “FDA” means United States Food and Drug Administration.
- DD. “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.
- EE. “Holder of the Reference Testosterone Gel Product Approval” means: (1) the person that received FDA approval to market the Reference Testosterone Gel Product, (2) a person owning or controlling the ability to enforce the patent(s) listed in the FDA Publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) in connection with any NDA for the Reference Testosterone Gel Product, or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licenses, licensors, successors, and assigns of each of the foregoing.
- FF. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- GG. “Manufacturing Designee” means any Person other than Respondents that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- HH. “Manufacture” means to manufacture or have manufactured (independent of Respondents) a Product in commercial quantities and in a manner consistent with cGMP; and have secure sources of supply (from sources other than Respondents) of active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in the Products Application(s) for such Product.

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- II. “Monitor” means any monitor appointed pursuant to this Order or the related Order to Maintain Assets.
- JJ. “NDC Numbers” means the National Drug Code numbers, including both the manufacturer’s FDA labeler code and the additional numbers assigned by an Application holder as a product code for a specific Product.
- KK. “NDA” means a New Drug Application, as defined under 21 U.S.C. §355(b), including all changes or supplements thereto which do not result in the submission of a new NDA.
- LL. “NDA Holder” means: (1) the person that received FDA approval to market a Product pursuant to an NDA, (2) a person owning or controlling the ability to enforce the patent(s) listed in the FDA Publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) in connection with the NDA, or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licenses, licensors, successors, and assigns of each of the foregoing.
- MM. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- NN. “Orders” means this Decision and Order and the Order to Maintain Assets.
- OO. “Paddock Divestiture Products” means all Products in Research and Development, manufactured, marketed or sold by Respondent Paddock pursuant to the following Product Approvals:

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1. ANDA No. A090490 (generic shampoo with the active ingredient ciclopirox at a dosage strength of 1%);
2. ANDA No. A040479 (generic rectal suppositories with active ingredient promethazine hydrochloride in dosage strengths of 12.5 and 25 mg);
3. ANDA No. A076829 (generic external cream with the active ingredient ammonium lactate at a dosage strength of 12%); and
4. ANDA No. A075575 (generic topical lotion with the active ingredient ammonium lactate at a dosage strength of 12%).

PP. “Par” means Par Pharmaceutical Companies, 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 at 300 Tice Boulevard, Woodcliff Lake, NJ 07677. For purposes of this Order, Par shall include any Person who succeeds Par as a party to the Relevant Toll Manufacturing Agreement.

QQ. “Patents” 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 existing as of the Closing Date, 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, related to any Divestiture Product that is owned by Respondents as of the Closing Date.

RR. “Perrigo ANDA Products” means the following Products in Research and Development by Respondent Perrigo:

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1. Products being developed pursuant to ANDA No. A091167 (generic spray with the active ingredient clobetasol at a dosage strength of .05%); and
 2. Products being developed as a generic equivalent to the brand-name product Pennsaid, a topical solution with the active ingredient diclofenac sodium at a dosage strength of 1.5% that is approved by the FDA under the New Drug Application (NDA) 020947.
- SS. “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.
- TT. “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.
- UU. “Product Application(s)” means ANDAs and other submissions to any national, international or local governmental regulatory authority for approvals, registrations, permits, licenses, consents, authorizations, or other approvals to research, develop, manufacture, distribute, finish, package, market, sell, store or transport a Product, together with all supplements, amendments, and revisions to such submissions, all preparatory work, drafts and data necessary for the preparation of such submissions, and all correspondence between Respondents and the relevant national, international or local governmental authority relating to such submissions.
- VV. “Product Approval(s)” means all approvals, registrations, permits, licenses, consents, authorizations, and other approvals by any national, international or local governmental regulatory authority, to research, develop, manufacture,

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distribute, finish, package, market, sell, store or transport a Divestiture Product, including without limitation, any ANDA approved by the FDA.

- WW. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefore (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the Divestiture Product(s).
- XX. “Proposed Acquirer” means Watson or any Person proposed by Respondents (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the Acquirer.
- YY. “Relevant Testosterone Gel Application(s)” means ANDA No. 79015, ANDA No. 91006 and/or NDA No. 203098 (transdermal gel with the active ingredient testosterone at a dosage strength of 1%).
- ZZ. “Relevant Testosterone Gel Products” means all Products in Research and Development, manufactured, marketed or sold by Respondent Paddock pursuant to a Relevant Testosterone Gel Applications.
- AAA. “Reference Testosterone Gel Product” means any Product identified by a Respondent as the Product upon which Respondent bases a Relevant Testosterone Gel Application.
- BBB. “Relevant Toll Manufacturing Agreement” means Amended and Restated Manufacturing and Supply Agreement between Par Pharmaceuticals, Inc. and Paddock Laboratories LLC, dated July ____ 2011 (attached hereto as non-public Appendix B).

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CCC. “Remedial Agreement(s)” means the following:

1. The Watson Remedial Agreements; or any other agreements between Respondents and an Acquirer (or between the Divestiture Trustee and an Acquirer) that have been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, and/or
2. Any agreement between Respondents and a Third Party to effect the assignment of assets or rights of Respondents related to a Divestiture Product for 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.

DDD. “Research and Development” means all preclinical and clinical drug development activities, including formulation, test method development and stability testing, toxicology, pharmacology, 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 any and all Product Approvals necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals); and registration and regulatory affairs related to the foregoing.

EEE. “Retained Product” means any Product(s) other than a Divestiture Product.

FFF. “Right of Reference or Use” means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining a Product Approval, including the ability to make available the underlying raw data from the investigation for FDA audit.

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GGG. “Third Party(ies)” means any non-governmental Person other than Respondents or an Acquirer of the Divestiture Products Assets.

HHH. “Watson Remedial Agreements” means all of the following agreements (attached hereto as non-public Appendix C):

1. “Asset Purchase Agreement” by and among Watson Pharmaceuticals, Inc. and Perrigo Company, dated as of May 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto; and
2. “Manufacturing and Supply Agreement” Watson Pharmaceuticals, Inc. and Perrigo Company, dated as of May 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto.

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

- A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Divestiture Products Assets and grant the Divestiture Products License, absolutely and in good faith, to Watson pursuant to, and in accordance with, the Watson Remedial Agreements;

provided, however, that if Respondents have divested the Divestiture Products Assets and granted the Divestiture Products License to Watson prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Watson is not an acceptable purchaser of the Divestiture Products Assets, then Respondents shall immediately rescind the transaction with Watson, in whole or in part, as directed by the Commission, and shall divest the Divestiture Products Assets and grant the Divestiture Products License within one hundred eighty (180)

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days from the date this Order becomes final, absolutely and in good faith, at no minimum price, to an Acquirer or Acquirers that receive(s) the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, that if Respondents have divested the Divestiture Products Assets and granted the Divestiture Products License to Watson prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Divestiture Products Assets or grant of the Divestiture Products License, as applicable, to Watson (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.

- B. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the Divestiture Products Assets and grant the Divestiture Products License to the Acquirer, and to permit the Acquirer to continue the Research and Development, manufacture, sale, marketing or distribution of the Divestiture Products;

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

- C. Respondents shall deliver the materials to be divested and licensed pursuant to this Order to the Acquirer (or at the option of the Acquirer, the Acquirer's Manufacturing Designee) in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring

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no unreasonable delays in transmission), and meaningful manner.

D. Until Respondents complete the divestitures required by this Paragraph, including transferring the Divestiture Products Assets and granting the Divestiture Products License(s), Respondents:

1. shall take such actions as are necessary to:
 - a. maintain the full economic viability and marketability of the Divestiture Products Businesses;
 - b. minimize any risk of loss of competitive potential of the Divestiture Products Businesses;
 - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Divestiture Products Businesses;
 - d. ensure the Divestiture Products Assets are provided to the Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to any Divestiture Product;
 - e. ensure the completeness of the transfer and delivery of the Divestiture Products Manufacturing Technology; and
2. 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 Divestiture Products Businesses,

provided that these obligations shall cease as to any particular Divestiture Product when Respondents have

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transferred to the Acquirer all assets and materials related to such product and have no further obligations regarding such product under any Contract Manufacturing Agreement.

- E. Respondents shall provide the Acquirer(s) with the assistance and advice reasonably necessary to enable the Acquirer(s) to engage in the Divestiture Products Businesses in a manner at least consistent with the past practice and expertise of Respondents. The advice and assistance required by this provision shall be provided at no greater than Direct Cost and shall include, without limitation, the following:
1. Designating employees knowledgeable about the Divestiture Products Manufacturing Technology used to manufacture each Divestiture Product who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee (if applicable) and the Monitor for the purpose of effectuating the terms of this Order, including but not limited to, assisting in the transfer of the Divestiture Products and resolving any issues related to Respondents' obligations under the Order;
 2. Preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to each of the Divestiture Products 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 Divestiture Products Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee;

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4. Making available to the Acquirer employees with knowledge of the Research and Development, manufacture, Product Applications and Product Approvals for the Divestiture Products; and
 5. Providing, in a timely manner, such other assistance and advice as is needed to enable the Acquirer or its Manufacturing Designee to:
 - a. manufacture each Divestiture Product in the quality and quantities achieved by the Respondents;
 - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell each Paddock Divestiture Product in commercial quantities and to obtain all Product Approvals for each such Divestiture Product; and
 - c. receive, integrate, and use all Divestiture Products Manufacturing Technology and all Divestiture Products Intellectual Property.
- F. At the option of the Acquirer, Respondent Perrigo shall manufacture and supply the Contract Manufactured Products to the Acquirer pursuant to a Contract Manufacturing Agreement that is entered into on or before the Closing Date. This agreement shall be subject to the following:
1. Respondent Perrigo shall give priority to manufacturing and supplying the Contract Manufactured Products to the Acquirer over manufacturing and supplying Products for Respondents' own use or sale;
 2. Each Respondent shall represent and warrant to the Acquirer that it shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by that Respondent to perform the duties required of it under this Order,

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including, in the case of Respondent Perrigo, any failure to deliver the Contract Manufactured Products in a timely manner as required by the Contract Manufacture Agreement unless the Respondent can demonstrate that such failure was entirely beyond the control of the Respondent and in no part the result of negligence or willful misconduct by the Respondent;

provided, however, that the Contract Manufacture Agreement may contain limits on each Respondent's aggregate liability for such a breach;

3. With respect to any Contract Manufactured Products to be marketed or sold in the United States of America, Respondent Perrigo shall 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 Manufactured Products to meet cGMP. Paddock shall 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 any of the Contract Manufactured Products, if any, that it manufactured to meet cGMP. This obligation may be made contingent upon the Acquirer giving Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, that Respondents may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with Respondents' responsibilities to supply the ingredients and/or components in the manner required by this Order;

provided, further, that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the

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Acquirer that exceed the representations and warranties made by Respondents to the Acquirer;

provided further that the Contract Manufacture Agreement may contain limits on Respondents' aggregate liability resulting from the failure of the Contract Manufactured Products to meet cGMP;

4. During the term of the Contract Manufacture Agreement, upon written request of the Acquirer or the Monitor (if any has been appointed), Respondents shall make available all data, information and records that relate to the manufacture of the Contract Manufactured Products generated or created after the Closing Date;
5. Respondent Perrigo shall maintain manufacturing facilities necessary to manufacture each Contract Manufactured Product in finished form, i.e., suitable for sale to the ultimate consumer/patient, until Respondent Perrigo has no further obligation to continue manufacture and supply of such product under the terms of this Order.
6. Respondent Perrigo shall continue to supply and manufacture a given Contract Manufactured Product until the earliest of the following:
 - a. Acquirer obtains all necessary Product Approvals to market and sell such Product in the United States and has the capability to Manufacture such Product using the same active pharmaceutical ingredients in all dosage strengths and presentations marketed and sold by Respondents, including without limitation, having all facilities, equipment, methods and processes qualified and validated for the Manufacture of such product; or
 - b. Acquirer notifies the Commission and Respondents of its intention to abandon its

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efforts to manufacture such Divestiture Product; or

- c. Staff of the Commission provides written notification to Respondents that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture such Divestiture Product; or
- d. Eighteen (18) months after the Closing Date, *provided, however,* that the Monitor, in consultation with staff of the Commission, may, as necessary to fulfill the remedial purposes of this Order, authorize up to three six (6) month extensions of Respondents' obligation to manufacture and supply a Contract Manufactured Product.

G. With respect to all NDC Numbers (including FDA Labeler Codes) used in the Divestiture Products Businesses ("Former NDC Number(s)") Respondents shall:

- 1. not seek to have any customer cross-reference a Former NDC Number with an NDC Number for a Retained Product, and shall inform the Acquirer of any such cross-referencing that is discovered by Respondents;
- 2. not interfere with efforts by the Acquirer to have a customer cease cross-referencing a Former NDC Number with the NDC Number of a Retained Product;
- 3. not interfere with efforts by the Acquirer to have a customer cross-reference a Former NDC Number with the NDC Number used by the Acquirer for a Divestiture Product; and
- 4. pursuant to the manner and timing reflected in the Remedial Agreements,

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- a. discontinue the use of the Former NDC Numbers in the sale or marketing of the Divestiture Products except for returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Acquisition Date and except as may be required by applicable Law; and
 - b. obtain approval from the Acquirer for any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of the Former NDC Numbers by Respondents prior to such notification(s) being disseminated to the customer(s).
- H. Respondents shall include in a Remedial Agreement a representation from the Acquirer that such Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each Divestiture Product and to have any such manufacture to be independent of Respondents, all as soon as reasonably practicable.
- I. Respondents shall:
 1. not directly or indirectly use any Confidential Business Information related exclusively to one or more Divestiture Products other than as necessary to comply with the requirements of this Order, Respondents' obligations to the Acquirer under the terms of any Remedial Agreement, or applicable Law;
 2. not directly or indirectly disclose or convey any Confidential Business Information related exclusively to one or more Divestiture Products to any Person except the Acquirer or other Persons specifically authorized by the Acquirer to receive such information; and

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3. maintain the confidentiality of any Confidential Business Information related to one or more Divestiture Products with the same degree of care and protection as used to protect the Confidential Business Information of Respondents.
- J. Respondents shall not enforce any agreement against a Third Party or the Acquirer to the extent that such agreement may limit or otherwise impair the ability of the Acquirer to acquire or use any Divestiture Products Manufacturing Technology. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to the Divestiture Products Manufacturing Technology. Further, not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to an agreement as described in this paragraph, which release shall allow the Third Party to provide the relevant Divestiture Products Manufacturing Technology to the Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to such Acquirer.
- K. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Acquirer for the Research and Development, manufacture, use, import, export, distribution, or sale of any Divestiture Product under any patents that
1. are owned or licensed by Respondents as of the day after the Acquisition Date that claim a method of making, using, or administering, or a composition of matter, relating to one or more Divestiture Products, or that claim a device relating to the use thereof; or
 2. are owned or licensed at any time after the Acquisition Date by Respondents that claim any aspect of Research and Development, manufacture, use, import, export, distribution, or sale of one or more Divestiture Products, other than such patents

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that claim inventions conceived by and reduced to practice after the Acquisition Date;

if such suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) Research and Development, or manufacture of one or more Divestiture Products; or (2) the use, import, export, supply, distribution, or sale of one or more Divestiture Products within the territory of the United States of America.

Respondents shall also covenant to the Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the Patents described in the immediately preceding paragraph, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Acquirer under such patents, if such suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) Research and Development, or manufacture of one or more Divestiture Products; or (2) the use, import, export, supply, distribution, or sale of one or more Divestiture Products within the territory of the United States of America.

- L. Upon reasonable written notice and request from an Acquirer to Respondent Perrigo, Respondent Perrigo shall provide, at no greater than Direct Cost, in a timely manner, assistance of knowledgeable employees of Respondent Perrigo to assist the Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Divestiture Products Intellectual Property, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (1) Research and Development, or manufacture of one or more Divestiture Products; or (2) the use, import, export, supply, distribution, or sale of one or more Divestiture Products within the territory of the United States of America.

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- M. For any patent infringement suit in which either Respondent is alleged to have infringed a Patent of a Third Party prior to the Closing Date where such a suit would have the potential to interfere with the Acquirer's freedom to practice the Research and Development, or manufacture of one or more Divestiture Products anywhere in the world; or the use, import, export, supply, distribution, or sale of one or more Divestiture Products within the territory of the United States of America, Respondents shall:
1. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondents in connection with obtaining resolution of any pending patent litigation involving such Divestiture Product;
 2. waive conflicts of interest, if any, to allow the Respondents' outside legal counsel to represent the relevant Acquirer in any ongoing patent litigation involving such Divestiture Product; and
 3. permit the transfer to the Acquirer of all of the litigation files and any related attorney work-product in the possession of Respondents' outside counsel relating to such Divestiture Product.
- N. Respondents shall not, in the territory of the United States of America,
1. use the Product Trademarks contained in the Divestiture Products Intellectual Property or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark;
 2. attempt to register such Product Trademarks;
 3. attempt to register any mark confusingly similar to such Product Trademarks;

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4. challenge or interfere with the Acquirer's use and registration of such Product Trademarks; or
5. challenge or interfere with the Acquirer's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

provided however, that this paragraph shall not preclude Respondents from continuing to use all trademarks, trade names, or service marks that have been used in commerce on a Retained Product at any time prior to the Acquisition Date.

O. The purpose of this Order is:

1. To ensure the continued use of Divestiture Products in the Divestiture Products Business independent of Respondents;
2. To create a viable and effective competitor in the Divestiture Products Business that is independent of the Respondents; 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

- A. Until the Closing Date, Respondents shall provide all Divestiture Product Employees with reasonable financial incentives to continue in their positions and to continue the Divestiture Products Businesses in a manner consistent with past practices and/or as may be necessary to preserve the existing marketability, viability and competitiveness of the Divestiture Products and to ensure successful execution of the pre-Acquisition plans for such Divestiture Products.

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- B. Until Respondent Perrigo fully transfers and delivers to the Acquirer the Divestiture Products Assets and grants the Divestiture Products License, Respondent Perrigo shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated with the Divestiture Products for the relevant Divestiture Products' last fiscal year.
- C. For a period lasting until six (6) months after the Closing Date, each Respondent shall
 - 1. not later than ten (10) days after written request by the Acquirer or Proposed Acquirer, or staff of the Commission, provide, to the extent permitted by Law, the Acquirer with the following information with respect to Persons employed by such Respondent:
 - a. a complete and accurate list containing the name of each Divestiture Product Employee (including former employees who were employed by Respondents within ninety (90) days of the execution date of any Remedial Agreement); and
 - b. with respect to each such employee,
 - i. the date of hire and effective service date;
 - ii. job title or position held; and
 - iii. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, Respondents may provide the employee's most recent performance appraisal.
 - 2. not interfere with the hiring or employing by the Acquirer or its Manufacturing Designee of any Divestiture Products Employees or make any counteroffer to a Divestiture Products Employee

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who has received a written offer of employment from an Acquirer or its Manufacturing Designee; and remove any impediments within the control of the Respondent that may deter a Divestiture Products Employee from accepting employment with an Acquirer or its Manufacturing Designee, including, but not limited to, removing non-competition or non-disclosure provisions of employment or other contracts with a Respondent that may affect the ability or incentive of a Divestiture Products Employee to be employed by an Acquirer or its Manufacturing Designee.

3. if requested by a Divestiture Products Employee, provide such employee with any requested records concerning his or her salary and benefits, including but not limited to, his or her base salary or current wages; his or her most recent bonus paid, aggregate annual compensation for the relevant Respondents' last fiscal year and current target or guaranteed bonus (if any); any material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and copies of all employee benefit plans and summary plan descriptions (if any) applicable to such employee.

D. For a period lasting until one (1) year after Closing Date, Respondents shall not:

1. 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 ("Covered Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or
2. hire such Covered Employee;

provided, however, Respondents may hire any former Covered Employee whose employment has been

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terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with Respondents, as long as such employee was not solicited in violation of the terms of the Order; and

provided further, that Respondents may advertise for employees in newspapers, trade publications or other media not targeted specifically at Covered Employees; or hire a Covered Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from Respondents.

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

- A. Respondents shall relinquish, at the Acquisition Date, all rights to receive, and shall not receive, the payment of any Service Fee (as that term is defined in the Androgel Backup Supply Agreement) that may accrue after the initial term of the Androgel Backup Supply Agreement, which ends September 30, 2012. Not later than ten (10) days after the Acquisition Date, Respondents shall provide written notice to Par that it relinquishes all rights to receive the payment of a Service Fee pursuant to this paragraph, and shall provide a copy of such written notice to the Commission and to the Monitor.
- B. For so long as an agreement for the actual or potential production by Perrigo of AndroGel remains in force under the Androgel Backup Supply Agreement, any extension of that agreement, or any new agreement, Respondents shall, after the Acquisition Date, not enter into any agreement with a Holder of the Reference Testosterone Gel Product Approval pursuant to which Respondents receive anything of value in exchange for their agreement to refrain from researching, developing, manufacturing, marketing or selling any Relevant Testosterone Gel Product, or

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taking any other action that otherwise deters, prevents, or inhibits Respondents' ability to manufacture, market or sell any Relevant Testosterone Gel Product immediately on or after the date Respondents receive Product Approval for such Relevant Testosterone Gel Product from the FDA; provided, however, that nothing in this paragraph shall prohibit a resolution or settlement of a patent infringement claim in which the consideration provided by the Holder of the Reference Testosterone Gel Product Approval to Respondents as part of the resolution or settlement includes only one or more of the following: (1) the right to market the Relevant Testosterone Gel Product in the United States prior to the expiration of (a) any patent that is the basis for the patent infringement claim, or (b) any patent right or other statutory exclusivity that would prevent the marketing of the Relevant Testosterone Gel Product; (2) a payment for reasonable litigation expenses not to exceed \$2,000,000; (3) a covenant not to sue on any claim that the Relevant Testosterone Gel Product infringes a United States patent.

- C. Respondents shall not modify or amend the Relevant Toll Manufacturing Agreement without the prior approval of the Commission.

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

- A. The Commission may appoint a monitor or monitors ("Monitor") to assure that Respondents expeditiously comply with all obligations and perform all responsibilities required by the Orders and the Remedial Agreements.
- B. The Commission appoints F. William Rahe as Monitor and approves the Monitor Agreement between F. William Rahe and Respondents, attached as Appendix A.

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- C. The Monitor's duties and responsibilities shall include the following:
1. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
 2. The Monitor shall have the power and authority to monitor Respondents' compliance with the Orders, and shall exercise such power and authority and carry out his or her duties and responsibilities in a manner consistent with the purposes of the Orders and in consultation with the Commission or its staff;
 3. The Monitor shall, in his or her sole discretion, consult with Third Parties in the exercise of his or her duties under the Orders or any agreement between the Monitor and Respondents; and
 4. The Monitor shall evaluate the reports submitted to the Commission by Respondents pursuant to the Orders and the Consent Agreement, and within thirty (30) days from the date the Monitor receives a report, report in writing to the Commission concerning performance by Respondents of its obligations under the Orders.
- D. Respondents shall grant and transfer to the Monitor, and such Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities, including but not limited to the following:
1. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with the Orders;
 2. Subject to any demonstrated legally recognized privilege, Respondents shall provide the Monitor full and complete access to personnel, books, documents, records kept in the ordinary course of

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business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with the Orders;

3. Respondents shall deliver to the Monitor a copy of each report submitted to the Commission pursuant to the Orders or the Consent Agreement;
4. The Monitor shall serve, without bond or other security, at the expense of Respondent Perrigo, on such reasonable and customary terms and conditions to which the Monitor and Respondent Perrigo agree and that the Commission approves;
5. The Monitor shall have authority to use the services of or employ, at the expense of Respondent Perrigo, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
6. Respondents shall indemnify the Monitor and hold the Monitor harmless to the extent set forth in the Monitor Agreement executed on May 13, 2011; and
7. Respondents may require the Monitor and each of the 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 Monitor from providing any information to the Commission or require the Monitor to report to Respondents the substance of communications to or from the Commission or the Acquirer.

- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality

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agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.

- F. The Monitor shall serve until Respondents fully and finally transferred Divestiture Products Assets, granted the Divestiture Products License, and fulfilled all obligations under this Order to provide assistance, and manufacture and supply the Contract Manufacture Products.
- G. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed substitute Monitor, Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor.
- H. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- I. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

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

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture Products Assets and Divestiture Products License as required by

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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, Respondents 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 Respondents to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have 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 Respondents of the identity of any proposed Divestiture Trustee, Respondents 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, Respondents 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.

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- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents 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. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the

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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 Respondents' 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 Respondents from among those approved by the Commission; *provided further*, that Respondents 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 Perrigo, 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 Perrigo, 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 incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture

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Trustee's services, all remaining monies shall be paid at the direction of Respondent Perrigo, 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 Perrigo 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 Monitor pursuant to the relevant provisions of the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondent Perrigo and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondents 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*, such agreement

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shall not restrict the Divestiture Trustee from providing any information to the Commission.

- E. 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.
- F. 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.

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

- A. Each Remedial Agreement shall be incorporated by reference into this Order, made a part hereof. Further, nothing in any Remedial Agreement shall limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of an Acquirer or to reduce any obligations of Respondents under a Remedial Agreement. Respondents shall comply with the terms of each Remedial Agreement, and a breach by Respondents of any term of a Remedial Agreement shall constitute a violation of this Order. To the extent that any term of a Remedial Agreement conflicts with a term of this Order or the Order to Maintain Assets such that Respondents cannot fully comply with both, Respondents shall comply with the Order or the Order to Maintain Assets.
- B. Respondents shall include in each Remedial Agreement a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the

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full scope and breadth of Respondents' obligations to the Acquirer pursuant to this Order.

- C. Prior to the Closing Date, Respondents shall not modify or amend any material term of any Remedial Agreement without the prior approval of the Commission. Further, any failure to meet any material condition precedent to closing contained in any Remedial Agreement (whether waived or not) shall constitute a violation of this Order.
- D. After the Closing Date and during the term of each Remedial Agreement, Respondents shall provide written notice to the Commission not more than five (5) days after any modification (material or otherwise) of the Remedial Agreement. Further, Respondents shall seek Commission approval of such modification (material or otherwise) within ten (10) days of filing such notification. If the Commission denies approval, the Commission will notify Respondents and Respondents shall expeditiously rescind the modification or make such other changes as are required by the Commission.
- E. Respondents 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 the Orders or the remedial purposes thereof.

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

- A. Within five (5) days of the Acquisition, Respondent Perrigo shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Before the Closing Date, Respondents shall submit to staff of the Commission a verified written report

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setting forth in detail the procedures Respondent Perrigo has implemented to:

1. reasonably ensure that all employees and representatives who have or may be exposed to Confidential Business Information understand and are required to comply with the confidentiality obligations contained in Paragraph II.I; and
2. reasonably ensure that all employees and representatives of Respondents, including those hired during the term of the Order, understand and are required to comply with all terms of this Order that are relevant to their job duties.

In further compliance with this provision, Respondents shall provide staff of the Commission with written notice of all changes, additions and modifications to the procedures implemented, and shall include specific information detailing their efforts to comply with this paragraph in all reports of compliance required by this Order;

provided, however, that Respondent Paddock shall have further no obligations under this paragraph after the Acquisition Date.

- C. Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order,
1. within sixty days after submitting the last report required by the Order to Maintain Assets, and every sixty (60) days thereafter until Respondents have fully complied with their obligations under Paragraphs II.A – II.F of the Order, and shall submit at the same time a copy of the report to the Monitor; and
 2. one (1) year after the date this Order becomes final, annually for the next nine years on the

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anniversary of the date this Order becomes final, and at other times as the Commission may require (Respondents are not required to submit these reports to the Monitor).

Respondents shall include in the compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with the Orders, including a full description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all Persons contacted, and shall make available to the Commission and the Monitor all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations;

provided, however, that Respondent Paddock shall have no further obligations under this paragraph after the Acquisition Date.

IX.**IT IS FURTHER ORDERED** that

- A. 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 Respondents, Respondents shall, without restraint or interference, permit any duly authorized representative of the Commission:
 - 1. access, during business office hours of Respondents 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 such Respondents related to compliance with this Order, which copying services shall be provided by such Respondents at the request of the authorized representative(s) of

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the Commission and at the expense of such Respondents; and

2. to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

X.

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

A. dissolution of Respondents;

B. acquisition, merger or consolidation of Respondents; or

C. any other change in Respondents 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.

XI,

IT IS FURTHER ORDERED that this Order shall terminate on June 21, 2022.

By the Commission, Commissioner Ohlhausen not participating.

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APPENDIX A**MONITOR AGREEMENT (WITHOUT NON-PUBLIC
EXHIBIT)****MONITOR AGREEMENT**

This Monitor Agreement ("Monitor Agreement") entered into among Quantic Regulatory Services, LLC ("Monitoring Firm" or "Quantic"), Perrigo Company (together with its affiliates and/or subsidiaries, "Perrigo"), Paddock Laboratories, Inc. ("Paddock" and, together with Perrigo, the "Respondents"), F. William Rahe, as an individual Monitor (as defined below) and R. Owen Richards, provides as follows:

WHEREAS, the United States Federal Trade Commission (the "Commission"), is evaluating whether to accept for Public Comment an *Agreement Containing Consent Orders*, incorporating a Decision and Order ("Decision and Order") and an Order to Maintain Assets, with Perrigo and Paddock (collectively, the "Orders"), which, among other things, require Perrigo to divest or transfer certain defined assets and Respondents to maintain those assets pending such divestiture or transfer, and provide for the appointment of one or more Monitors to ensure that Respondents comply with their respective obligations under the Orders;

WHEREAS, the Commission may appoint Mr. Rahe of Quantic as Monitor, and provide that he may seek assistance as needed, including the assistance of Mr. Richards of Quantic, pursuant to the Orders to monitor Respondents' compliance with the terms of the Consent Agreement and Orders and with the Remedial Agreement referenced in the Orders, and to monitor the efforts of the Commission-approved Acquirers (as defined in the Orders) to obtain all necessary FDA approvals and to complete the technology

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transfers of all Divested Products, as applicable, and Mr. Richards and Mr. Rahe, each pursuant to his Consulting Agreement with the Monitoring Firm, consented to such appointment and agrees to serve pursuant to the terms of his Consulting Agreement with the Monitoring Firm and this Agreement;

WHEREAS, the Orders further provide or will provide that Respondents shall execute a Monitor Agreement, subject to the prior approval of the Commission, conferring all the rights, powers and authority necessary to permit the Monitor to carry out such duties and responsibilities pursuant to the Orders;

WHEREAS, this Monitor Agreement conforms or will conform with the requirements of the Orders and does not contradict the Orders;

WHEREAS, this Monitor Agreement, although subject to Commission approval, is effective for any purpose, including but not limited to imposing rights and responsibilities on Respondents, the Monitoring Firm or the Monitor under the Orders, upon execution by the parties; and

WHEREAS, the parties to this Monitor Agreement intend to be legally bound;

NOW, THEREFORE, the parties agree as follows:

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1. Capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Consent Agreement and the Orders. The term "Divestiture Products" means the Divestiture Products as defined in the Consent Agreement.
2. The Monitor and the Monitoring Firm shall have all of the powers, responsibilities and protections conferred upon the Monitor by the Orders, including but not limited to:
 - a. monitoring the transfer of the Divestiture Products Assets to the Commission-approved Acquirers;
 - b. monitoring any redaction and use of Confidential Business Information retained by Respondents as required by the Orders; and
 - c. monitoring the performance of any transition services, including Contract Manufacture, required by the Orders.
3. Respondents hereby agree that, upon execution by all parties of this Monitor Agreement, Respondents will comply fully with all terms of the Orders requiring them to confer all rights, powers, authority and privileges upon the Monitor and the Monitoring Firm, or to impose upon themselves any duties or

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obligations with respect to the Monitor, to enable the Monitor to perform the duties and responsibilities of the Monitor thereunder.

4. Respondents, individually or together (as applicable) further agree with the Monitoring Firm and the Monitor that:
 - a. they will use their best efforts to ensure that any Commission-approved Acquirer works with the Monitor starting at or about the Closing Date to facilitate the Monitor's fulfillment of his duties under the Orders and the exchange of information between the Commission-approved Acquirer and the Monitor;
 - b. no later than ten (10) business days after the Commission approves this Monitor Agreement, Respondents will provide the Monitor with the following, as applicable:
 - (1) a complete inventory and description of the Divestiture Products, identifying, in particular, those Divestiture Products which may require actions to maintain their viability and marketability, and the person(s) responsible for taking those actions;
 - (2) a complete inventory of all existing FDA approvals and pending FDA approvals for the Products included in the Divestiture

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Products identifying actions required to maintain or complete such approvals and identifying the person(s) responsible for taking such actions;

- (3) a complete inventory of all activities or operations worldwide that relate to the manufacture of the Divestiture Products, and which relate to Respondents' compliance with the Orders, including processes and process validations which are under development, identifying the person(s) responsible for maintaining or pursuing such activities and giving an inventory of materials and records relating to such manufacture;

- (4) a complete inventory of all activities or operations worldwide that relate to the Research and Development of the Perrigo ANDA Products, and which relate to Respondents' compliance with the Orders, including processes and process validations which are under development, identifying the person(s) responsible for maintaining or pursuing such activities, and giving an inventory of materials and records relating to such manufacture;

- (5) full and complete details of all dealings with any future Commission-approved Acquirer of the Divestiture Products, including copies of all correspondence and written reports of all

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contacts and discussions with any such future Commission-approved Acquirer and any draft and/or executed complete agreements, including any attached exhibits, schedules and appendices; and

- (6) a complete inventory of all Divestiture Products Intellectual Property included in the Divestiture Products Assets related to the manufacture or sale of the Divestiture Products in the United States, identifying actions needed to maintain such applicable intellectual property and the person(s) responsible for such actions;
- c. they will each designate a senior individual as a primary contact for the Monitor, provide a written list of the principal individuals to be involved in the transitioning of the Divestiture Products to the Commission-approved Acquirers, together with their locations, telephone numbers, electronic mail addresses (if available), and responsibilities, and provide the Monitor with written notice of any changes in such personnel occurring thereafter;
- d. they will, in consultation with the Monitor, identify employees who possess know-how, trade secrets and other business information used in the manufacture of the Divestiture Products and will ensure that those employees are reasonably available as needed to provide assistance to the Acquirer as required under the Orders;

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- e. they will provide the Monitor with prompt notification of significant meetings, including date, time and venue, scheduled after the execution of this Monitor Agreement, relating to the development, manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Divestiture Products, and such meetings may be attended by the Monitor or his representative, at the Monitor's option or at the request of the Commission or staff of the Commission;
- f. they will provide the Monitor with the minutes, if any, of the above-referenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of the Respondents;
- g. they will provide the Monitor with all correspondence, meeting minutes, telephone summaries, or reports sent to or received from the FDA relating to the Divestiture Products;
- h. they will provide the Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Consent Agreement and the Orders, simultaneous with the submission of such reports to the Commission;
- i. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Orders, they will provide

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every (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or as reasonably requested by the Monitor, electronic or hard copy reports to the Monitor reasonably describing Respondents' activities and obligations under the Orders concerning the Divestiture Products including, without limitation, to the extent applicable:

- (1) all significant activities concerned with the manufacture, supply and technology transfer of the relevant Products that are identified in the Divestiture Products, including, without limitation, negotiation and operation of supply agreements, actual supply, and inventory; and
- (2) all minutes and records of significant meetings, action plans, and follow-ups to action plans and meetings with the Commission-approved Acquirers related to the manufacture, supply, and technology transfer of the Products identified in the Divestiture Products; and
- ~~(3) all significant activities concerning the assistance, advice and~~
consultation provided to any Commission-approved Acquirer generally as provided in the Orders;

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provided, however, that, at the time the Orders become final, the reports described in this paragraph shall be due to the Monitor either as requested by the Monitor or within five (5) business days of the date that Respondents file Respondents' reports with the Commission as required pursuant to the Orders;

- j. on request, they will provide the Monitor with any and all records that relate to the manufacture of the Products identified in the Divestiture Products with the right to use them to achieve the purposes of the Orders;
- k. they will comply with the Monitor's requests for onsite visits and audits of Respondents' facilities (or any contract manufacturer's facility) used to manufacture the Products identified in the Divestiture Products;
- l. they will comply with the Monitor's reasonable requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Monitor pursuant to this Agreement or in connection with any matters the Monitor deems reasonably necessary to perform its responsibilities under the Orders, including, without limitation, as applicable, meetings and discussions with the principal staff involved in any activities relating to the research, development, manufacture, sale and/or divestiture of the Divestiture Products or any Product comprised therein and, further including, actions necessary to maintain all necessary

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- FDA approvals to manufacture and sell any of the Divestiture Products, to maintain the viability and marketability of the Divestiture Products, as well as the tangible assets of the facilities used to manufacture and sell all of the Divestiture Products, and to prevent the destruction, removal, wasting, deterioration or impairment of the Divestiture Products, and they will provide the Monitor with access to and hard and electronic copies of all other data, records, or other information that the Monitor believes are necessary to the proper discharge of its responsibilities under the Orders;
- m. they will provide prompt notice of any meetings, activities or events affecting or likely to affect the maintenance of the Divestiture Products, including, but not limited to, any and all meetings or communications with the FDA; and
 - n. they will provide the Monitor with such other information, documents, and the like requested by the Monitor in order to carry out Monitor's responsibilities under this Monitoring Agreement and the Orders.
5. Respondents shall promptly notify the Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and Respondents related to the Orders or this Monitor Agreement, together with electronic or hard copies (or, in the case of

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oral communications, summaries), as may be requested by the Monitor, of such communications.

6. Respondents agree that to the extent authorized by the Orders, the Monitoring Firm and the Monitor shall have the authority to consult with and employ, at the expense of Perrigo, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitoring Firm and the Monitor's duties and responsibilities, including but not limited to supervising the transfer of Confidential Business Information.
7. Respondents and the Monitor understand and agree that the Commission or its staff may request, pursuant to and consistent with the Orders, that the Monitor investigates and/or audits Respondents' compliance with Respondents' obligations to maintain assets pursuant to the Orders, and submits such additional written or oral reports, under applicable confidentiality restrictions, to the Commission as the Commission or its staff may at any time request concerning Respondents' compliance with Respondents' obligations to maintain assets pursuant to the Orders. Respondents and the Monitor further understand and agree that the Commission or its staff may request assistance from the Monitor with respect to the content of the Orders prior to such Orders becoming final.

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8. The Monitoring Firm and the Monitor shall maintain the confidentiality of all information provided to the Monitor by Respondents. Such information shall be used by the Monitoring Firm and the Monitor only in connection with the performance of the Monitor's duties pursuant to this Agreement. Such information shall not be disclosed by the Monitoring Firm and the Monitor to any third party other than:
 - a. persons engaged, employed by, or working with, the Monitor under this Agreement;
 - b. any Commission-approved Acquirer to the extent that the information is of a non-privileged nature; or
 - c. persons employed at, or engaged by, the Commission and working on this matter.
9. Upon termination of the Monitor's duties under this Monitor Agreement, the Monitor and the Monitoring Firm each shall promptly return to Respondents all material provided to the Monitor by Respondents that is confidential to Respondents and that Respondents are entitled to have returned to Respondent under the Orders, and shall destroy any material prepared by the Monitor that contains or reflects any confidential information of Respondents provided that the Commission staff does not require the Monitor to maintain the materials,

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and provided, that, notwithstanding the foregoing, the Monitoring Firm shall be entitled to keep one copy of all such information and materials in its confidential files. Nothing herein shall abrogate the Monitor's and the Monitoring Firm's duty of confidentiality.

10. In addition, the Monitoring Firm and the Monitor shall keep confidential for a period of five (5) years all other aspects of the performance of its duties under this Monitor Agreement. To the extent that the Monitoring Firm or the Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Monitor in accordance with the Orders, the Monitoring Firm and the Monitor shall ensure that such persons execute an appropriate confidentiality agreement.

For the purposes of this Section and Sections 8, 9 and 10, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Monitoring Firm or the Monitor or by any employee, agent, affiliate or consultant of the Monitor), or to the extent that the recipient of such information can demonstrate that such information was already known to the recipient at the time of receipt or becomes known to the recipient from a source other than Respondents, or any director, officer, employee, agent, consultant or affiliate of Respondents, when such source is entitled to make such disclosure to such

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recipient or such information was independently developed by the Monitor as evidenced by written records.

11. Nothing in this Monitor Agreement shall require Respondents to disclose any material or information that is subject to a legally recognized privilege or that Respondents are prohibited from disclosing by reason of law or an agreement with a third party.
12. Neither the Monitor nor the Monitoring Firm shall have a fiduciary responsibility to the Respondents, but shall have fiduciary duties to the Commission.
13. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Orders as it relates to Respondents.
14. Perrigo will pay the Monitoring Firm in accordance with the fee schedule attached hereto as Confidential Exhibit A for all time spent in the performance of the Monitor's duties, including all monitoring activities related to the efforts of the Commission-approved Acquirers of the Divestiture Products (including any and all such activities performed prior to the date of this Agreement), all work in connection with the negotiation and preparation of this Monitor Agreement, and all reasonable and necessary travel time. Every six months

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such hourly rates should be reviewed and may be adjusted by agreement with Perrigo.

- a. In addition, Perrigo will pay all out-of-pocket expenses incurred by the Monitor in the performance of the Monitor's duties, including any auto, train, or air travel and all telecommunication charges incurred in the performance of the Monitor's duties.
- b. Any expense charged to a credit card incurred in a currency other than U.S. dollars shall be converted into dollars for expense reimbursement purposes at the exchange rate used for said credit card transaction and any ancillary cash expenses for which a credit card is not possible shall be converted at the exchange rate for which said currency was purchased.
- c. The Monitoring Firm and the Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to work permits, income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.

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15. Perrigo agrees to pay all fees, costs and expenses set forth under paragraph 14 within thirty (30) days of receipt of an invoice therefore.

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16. Perrigo hereby confirms its obligation to indemnify the Monitoring Firm and the Monitor and hold each of them harmless in accordance with the discharge of their duties under the Orders (and, upon direction by the Commission to the Monitor to divest any Divestiture Products).

Without in any way limiting the generality of the foregoing, Perrigo shall indemnify the Monitoring Firm and each of the Monitor and any subcontractor and their respective consultants, agents, partners, principals, directors, officers, members, managers and employees (the "Indemnified Parties") and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or expenses, 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, arising out of or in connection with the performance of the Monitor's duties and obligations, except to the extent that such losses, claims, damages, liabilities, or expenses are finally judicially determined to result from the willful misconduct or gross negligence of the Monitor. This section shall survive the expiration or termination of this Agreement.

Paddock shall indemnify the Indemnified Parties and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or

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expenses, 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, arising out of or in connection with the performance of the Monitor's duties and obligations prior to the closing of Perrigo's acquisition of Paddock, except to the extent that such losses, claims, damages, liabilities, or expenses are finally judicially determined to result from the willful misconduct or gross negligence of the Monitor. This section shall survive the expiration or termination of this Agreement.

17. The Monitor's and the Monitoring Firm's maximum liability to the Respondents relating to services pursuant to this Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the total sum of the fees paid to the Monitoring Firm by Perrigo, not to exceed \$250,000. In no circumstances whatsoever shall Monitor or Monitoring Firm be liable for any special, incidental, consequential, or punitive damages, unless they engage in willful misconduct. The Monitor is not responsible for evaluating the legal or technical sufficiency of any documents, materials or actions of Respondents or any Commission-approved Acquirers under the Orders. The Monitor or the Monitoring Firm shall not incur any liability of any nature for the failure of Respondents, the Commission-approved Acquirer, or the Commission to perform any acts, or not perform any acts. This section shall survive the termination or expiration of

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this Agreement. Each Respondent agrees that its obligations to indemnify the Monitoring Firm and the Monitor extend to (i) any agreement that is entered between the Monitor or the Monitoring Firm and any Commission-approved Acquirer and any action under this Monitor Agreement and the Orders related to the Commission-approved Acquirer(s) and (ii) any and all Monitor's and Monitoring Firm's responsibilities under this Monitor Agreement or the Orders. This section shall survive the termination or expiration of this Agreement.

18. Upon this Monitor Agreement becoming effective, the Monitor shall be permitted, and Respondents shall be required, to notify all current Commission-approved Acquirers and potential future Acquirers with respect to its appointment as Monitor.
19. In the event that a disagreement or dispute between Respondents and the Monitor or the Monitoring Firm cannot be resolved by the parties, any party may seek the assistance of the individual in charge of the Commission's Compliance Division to resolve this issue. In the event that such disagreement or dispute cannot be resolved by the parties, the parties shall submit the matter to binding arbitration before the American Arbitration Association under its Commercial Arbitration Rules, but only if the individual in charge of the Commission's Compliance Division determines within the Commission's reasonable discretion that such a matter is appropriate for submission to the

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American Arbitration Association. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Respondents' obligations pursuant to the Orders.

20. This agreement shall be subject to the substantive law of the State of New York (regardless of any other jurisdiction's choice of law principles).
21. This Monitor Agreement shall terminate when the Monitor has discharged his obligations under the Order. The FTC will consult with the Monitor to determine when the Respondents' obligations under the Order have terminated. The Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Orders. The confidentiality and indemnity obligations of this Monitor Agreement shall survive its termination.
22. It is understood that the Monitor will be serving under this Monitor Agreement as an independent contractor of the Monitoring Firm and that the relationship of employer and employee shall not exist between Monitor and Respondents.
23. This Agreement is for the sole benefit of the parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder.

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24. This Agreement contains the entire agreement between the parties hereto with respect to the matters described herein and replaces any and all prior agreements or understandings, whether written or oral.
25. Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by mail, reputable overnight courier or fax (with acknowledgment of receipt of such fax having been received), to the applicable party at its address below (or to such other address as to which such party shall hereafter notify the other party):

If to the Monitoring Firm, to:

Mr. R. Owen Richards
Quantic Regulatory Services, LLC
5N Regent Street, Suite 502
Livingston, NJ 07039
Telephone: 973-992-0505
Email: orichards@quanticgroup.com

If to the Monitor, to:

..... Mr. F. William Rahe
Quantic Regulatory Services, LLC
5N Regent Street, Suite 502
Livingston, NJ 07039

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Telephone: 317-331-3890

Email: wrahe@quanticgroup.com

If to Perrigo, to:

Mr. Andrew M. Solomon

Assistant General Counsel

Perrigo Company

515 Eastern Avenue

Allegan, MI 49010

Telephone: 269-686-7294

Email: Andrew.Solomon@perrigo.com

If to Paddock, to:

Mr. Phil Thompson

Vice President, General Counsel

Paddock Laboratories, Inc.

3940 Quebec Avenue North

Minneapolis, MN 55427

Telephone: 763-732-0214

Email: pthompson@paddocklabs.com

If to the Commission:

Federal Trade Commission

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601 New Jersey Avenue, NW

Washington, DC 20001

Attn: Ms. Susan Huber

Telephone: 202-326-3331

Email: shuber@ftc.gov

26. This Monitor Agreement shall become binding upon execution, although it will be subject to approval by the Commission.
27. This Monitor Agreement may be signed in counterparts.

Decision and Order

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 13 of May, 2011.

Quantic Regulatory Services, LLC:

R. Owen Richards, President

Quantic Regulatory Services, LLC

F. William Rahe, Monitor

Perrigo Company:



Raymond Canole, Vice President, Corporate Development

Paddock Laboratories, Inc.

Phil Thompson, Vice President and General Counsel

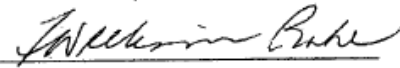
Decision and Order

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 13th of May, 2011.

Quantic Regulatory Services, LLC:

R. Owen Richards, President

Quantic Regulatory Services, LLC



F. William Rahe, Monitor

Perrigo Company:

Raymond Canole, Vice President, Corporate Development

Paddock Laboratories, Inc.

Phil Thompson, Vice President and General Counsel

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IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 12th of May, 2011.

Quantic Regulatory Services, LLC:

R. Owen Richards, President

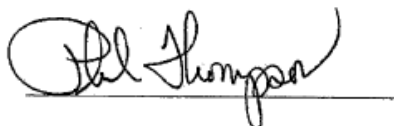
Quantic Regulatory Services, LLC

F. William Rahe, Monitor

Perrigo Company:

Raymond Canole, Vice President, Corporate Development

Paddock Laboratories, Inc.

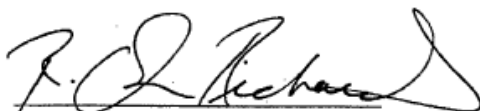
A handwritten signature in black ink, appearing to read "Phil Thompson", is written over a horizontal line.

Phil Thompson, Vice President and General Counsel

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IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 1st of May, 2011.

Quantic Regulatory Services, LLC:



R. Owen Richards, President

Quantic Regulatory Services, LLC

F. William Rahe, Monitor

Perrigo Company:

Raymond Canole, Vice President, Corporate Development

Paddock Laboratories, Inc.

Phil Thompson, Vice President and General Counsel

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NON-PUBLIC APPENDIX A-1

EXHIBIT TO THE MONITOR AGREEMENT

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

NON-PUBLIC APPENDIX B

RELEVANT TOLL MANUFACTURING AGREEMENT

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

NON-PUBLIC APPENDIX C

WATSON REMEDIAL AGREEMENTS

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

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**I. Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Perrigo Company (“Perrigo”) and Paddock Laboratories, Inc. (“Paddock”) that is designed to remedy the anticompetitive effects resulting from Perrigo’s acquisition of Paddock. Under the terms of the proposed Consent Agreement, the companies would be required to divest to Watson Pharmaceuticals, Inc. (“Watson”) Paddock’s rights and assets necessary to manufacture and market generic: (1) ammonium lactate external cream 12 percent (“ammonium lactate cream”); (2) ammonium lactate topical lotion 12 percent (“ammonium lactate lotion”); (3) ciclopirox shampoo 1 percent (“ciclopirox shampoo”); and (4) promethazine hydrochloride rectal suppository 12.5 mg and 25 mg (“promethazine suppository”). The proposed Consent Agreement also requires the companies to divest to Watson all of Perrigo’s rights and assets necessary to manufacture and market generic clobetasol propionate spray 0.05 percent (“clobetasol spray”) and diclofenac sodium topical solution 1.5 percent (“diclofenac solution”). Further, the proposed Consent Agreement prohibits the companies from accepting certain payments under a backup supply agreement between Paddock and Abbott Laboratories (“Abbott”) for Androgel, the branded version of testosterone gel 1 percent (“testosterone gel”), and entering into any “pay-for-delay” arrangements with Abbott.

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

Pursuant to a Purchase Agreement dated January 20, 2011, Perrigo plans to acquire substantially all of Paddock’s assets for

Analysis to Aid Public Comment

\$540 million. The Commission's Complaint alleges 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 FTC Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in the U.S. markets for the manufacture and sale of the following generic pharmaceuticals: (1) ammonium lactate cream; (2) ammonium lactate lotion; (3) ciclopirox shampoo; (4) promethazine suppository; (5) clobetasol spray; (6) diclofenac solution (collectively, the "Products"); and (7) testosterone gel. The proposed Consent Agreement will remedy the alleged violations in each of these markets.

II. The Products and Structure of the Markets

The proposed acquisition would reduce the number of generic suppliers in six generic drug markets. The number of generic suppliers has a direct and substantial impact on generic pricing, as each additional generic supplier can have a competitive impact on the market. Because there are multiple generic equivalents for each of the products at issue here and the branded products are substantially more expensive than the generic versions, the branded versions no longer significantly constrain the generics' pricing.

The proposed acquisition would reduce the number of competitors from three to two in four markets: (1) ammonium lactate cream; (2) ammonium lactate lotion; (3) ciclopirox shampoo; and (4) promethazine suppository. The structure of each of these markets is as follows:

- The ammonium lactate cream and lotion products are both prescription moisturizers used to treat dry, scaly skin conditions, and help relieve itching. In 2010, annual sales of ammonium lactate cream were approximately \$9.7 million, while sales of the ammonium lactate lotion totaled \$19 million. The same firms compete in both markets – Perrigo, Paddock, and Taro Pharmaceutical Industries Ltd. ("Taro"), although Paddock has temporarily withdrawn its products from the U.S. market. Perrigo leads the market for ammonium lactate cream with a 70 percent share in the United States. Paddock has 17 percent of the market and Taro has 12 percent. In the market for ammonium lactate

Analysis to Aid Public Comment

cream, the combined firm would account for 87 percent after the proposed acquisition. Perrigo and Paddock are the leading U.S. suppliers of ammonium lactate lotion, with 43 percent and 50 percent of the market, respectively. Taro has only captured a 5 percent market share to date. Post-acquisition, Perrigo's share would increase to 93 percent of the market.

- Ciclopirox shampoo is a prescription shampoo used to treat seborrheic dermatitis, an inflammatory condition that causes flaky scales and patches on the scalp. Paddock is the leading supplier in the \$14.5 million market for ciclopirox shampoo, with a share of approximately 83 percent. Perrigo, with a share of 16 percent, and E. Fougera & Co., with a 1 percent share, are the only other U.S. suppliers of the product. The proposed acquisition, therefore, would result in a combined market share of 99 percent.
- Promethazine suppository is indicated for a variety of uses, including to treat allergic reactions, to prevent and control motion sickness, and to relieve nausea and vomiting associated with surgery. Sales of the 12.5 mg and 25 mg strengths were approximately \$7.9 million and \$36.1 million in 2010, respectively. Perrigo, Paddock, and G&W Laboratories, Inc. ("G&W") are the only U.S. suppliers of both strengths. For the 12.5 mg strength, Perrigo has 15 percent of the market, Paddock has 19 percent, and G&W has 66 percent. For the 25 mg strength, Perrigo has 15 percent of the market, Paddock has 20 percent, and G&W has 65 percent. A combined Perrigo and Paddock would possess 34 percent of the 12.5 mg market and 35 percent of the 25 mg market.

Both Perrigo and Paddock also are developing products for two future generic drug markets: (1) clobetasol spray and (2) diclofenac solution. Clobetasol spray is a topical steroid used to treat moderate to severe psoriasis in adults. Diclofenac solution is a non-steroidal anti-inflammatory drug used to treat osteoarthritis of the knee. Perrigo and Paddock are among a limited number of suppliers that are capable of, and interested in, entering these

Analysis to Aid Public Comment

markets in a timely manner. Accordingly, the proposed acquisition would eliminate important future competition in these markets.

Finally, the proposed acquisition also could inhibit important future competition in the testosterone gel market. Testosterone gel, marketed by Abbott under the brand name Androgel, is a prescription gel used to treat adult males with a testosterone deficiency. Perrigo is one of a limited number of suppliers capable of entering this future generic market in a timely manner. Pursuant to an agreement between Par Pharmaceutical Companies, Inc. ("Par"), Paddock, and Solvay Pharmaceuticals, the former owner of Androgel, Par agreed to delay introducing a generic version of Androgel in exchange for, among other things, payments under a backup supply agreement. That agreement has since been transferred to Paddock. The proposed acquisition would make Perrigo a party to that agreement, thereby enhancing Abbott's and Perrigo's ability to coordinate to delay the introduction of Perrigo's product.

III. Entry

Entry into the markets for the manufacture and sale of the products would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and U.S. Food and Drug Administration ("FDA") drug approval requirements take a minimum of two years. Furthermore, entry would not be likely because many of the relevant markets are small, so the limited sales opportunities available to a new entrant would likely be insufficient to warrant the time and investment necessary to enter.

IV. Effects of the Acquisition

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for ammonium lactate cream, ammonium lactate lotion, ciclopirox shampoo, and promethazine suppository. In generic pharmaceutical markets, pricing is heavily influenced by the number of competitors that participate in a given market. The

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evidence shows that with the entry of each additional competitor, the prices of the generic products at issue have decreased. Customers consistently state that the price of a generic drug decreases with the entry of the second, third, and even fourth competitor. In these markets, the proposed acquisition would eliminate one of only three competitors. The evidence indicates that anticompetitive effects – both unilateral and coordinated – are likely to result from a decrease in the number of independent competitors in these markets, thereby increasing the likelihood that customers will pay higher prices.

The proposed acquisition also eliminates or delays important future competition between Perrigo and Paddock in the U.S. markets for clobetasol spray and diclofenac solution. Perrigo's and Paddock's independent entry into these markets likely would have resulted in lower prices for customers. The proposed acquisition would deprive customers of the expected price decrease that would occur upon the parties' entry into these markets.

Similarly, the proposed acquisition increases the likelihood and degree of coordinated interaction between Perrigo and Abbott in the U.S. testosterone gel market. Perrigo would become a party to the Par/Paddock backup supply agreement, thereby enhancing Abbott's and Perrigo's ability to coordinate to delay the introduction of Perrigo's product. Perrigo's independent entry into the market likely would result in lower prices for customers. The proposed acquisition could therefore deprive customers of the expected price decrease that would ensue upon Perrigo's timely entry into the market.

V. The Consent Agreement

The proposed Consent Agreement effectively remedies the acquisition's anticompetitive effects in the relevant product markets by requiring a divestiture of the Products to a Commission-approved acquirer no later than ten days after the acquisition. The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition.

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The Consent Agreement requires that the parties divest rights and assets related to the Products to Watson. Watson is the third largest generic drug manufacturer in the United States, and well-situated to manufacture and market the acquired products. Watson has extensive experience in the development, manufacturing, and distribution of generic pharmaceuticals, as well as experience transferring assets from other pharmaceutical companies. Watson has approximately 325 active products and an active product development pipeline. Moreover, Watson's acquisition of the divested assets does not in itself present competitive concerns because Watson does not compete, nor does it have plans to independently enter, any of the markets affected by the proposed transaction. With its resources, capabilities, strong reputation, and experience manufacturing and marketing generic products, Watson is well-positioned to replicate the competition that would be lost with the acquisition.

If the Commission ultimately determines that Watson is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures to Watson is not acceptable, the parties must unwind the sale and divest the Products within six months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six months, the Commission may appoint a trustee to divest the Product assets.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Perrigo and Paddock to provide transitional services to enable Watson to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Perrigo and Paddock. In addition, the parties must supply Watson with the Products pursuant to a supply agreement while they transfer the manufacturing technology to a third-party manufacturer of Watson's choice.

The Consent Agreement also preserves competition in the market for testosterone gel by prohibiting the parties from: (1) receiving any payments that accrue after the initial term of the backup supply agreement aside from those for manufacturing the

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product; and (2) entering into any anticompetitive pay-for-delay arrangements with Abbott regarding the testosterone gel product.

The Commission has appointed F. William Rahe of Quantic Regulatory Services, LLC (“Quantic”) as the Interim Monitor to oversee the asset transfer and to ensure Perrigo and Paddock’s compliance with the provisions of the proposed Consent Agreement. Mr. Rahe is a senior consultant at Quantic and has several years of experience in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Quantic clients on achieving satisfactory regulatory compliance and interfacing with the FDA. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires the parties to file reports with the Commission periodically until the divestitures and transfers are accomplished.

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.

INTERLOCUTORY, MODIFYING,
VACATING, AND MISCELLANEOUS
ORDERS
