

Complaint

IN THE MATTER OF

PRESTIGE BRANDS HOLDINGS, INC.
AND
INSIGHT PHARMACEUTICALS CORPORATION

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-4487; File No. 141 0159
Complaint, August 27, 2014 – Decision, October 7, 2014

This consent order addresses the \$750 million acquisition by Prestige Brands Holdings, Inc. of certain assets of Insight Pharmaceuticals Corporation. The complaint alleges that the acquisition violates Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening competition in U.S. markets for the manufacture, marketing, distribution, and sale of OTC motion sickness medications. The consent order requires Prestige to divest all of Insight's rights and assets related to its OTC motion sickness product, Bonine.

Participants

For the *Commission*: Christina Perez and David Von Nirschl.

For the *Respondents*: Debra Dermody, ReedSmith; Marin Boney and Mark Kovner, Kirkland & Ellis LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Prestige Brands Holdings, Inc. ("Prestige"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Insight Pharmaceuticals Corporation. ("Insight"), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the Federal Trade Commission Act ("FTC Act"), as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the

Complaint

public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Prestige is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its corporate head office and principal place of business located at 660 White Plains Road, Suite 250, Tarrytown, New York 10591.

2. Respondent Insight is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its corporate head office and principal place of business located at 900 Northbrook Drive, Suite 200, Trevose, Pennsylvania 19053.

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

II. THE PROPOSED ACQUISITION

4. Pursuant to a Stock Purchase Agreement dated April 25, 2014 (the “Agreement”), Medtech Products Inc. (“Medtech”), a subsidiary of Prestige, intends to purchase all of the outstanding shares of Insight for approximately \$750 million (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKET

5. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is the manufacture, marketing, distribution, and sale of over-the-counter (“OTC”) motion sickness medications.

Complaint

6. For the purposes of this Complaint, the United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in the relevant line of commerce.

IV. THE STRUCTURE OF THE MARKETS

7. Prestige and Insight are the two leading suppliers of branded OTC motion sickness medication in the United States and each other's closest competitor. The only other branded OTC motion sickness medication supplier has minimal sales. Private label OTC motion sickness products account for a substantial share of sales, but they have only a limited competitive impact in the market because they are usually priced at a fixed discount to branded OTC motion sickness medication products, and are not promoted or marketed. The Acquisition would substantially increase the Herfindahl-Hirschman Index.

V. ENTRY CONDITIONS

8. Entry into the relevant market described in Paragraphs 5 and 6 would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects of the Acquisition. Given the limited sales opportunities available in the U.S. OTC motion sickness medication market, potential new entrants are unlikely to incur the high up-front investment costs required to establish a recognized brand and compete effectively. A potential new entrant would also find it difficult to convince retailers to replace established brands in the limited shelf space they allocate to OTC motion sickness products.

VI. EFFECTS OF THE ACQUISITION

9. The effects of the Acquisition, if consummated, may be substantially to lessen competition, or tend to create a monopoly, in the relevant market 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, by, among other things, eliminating actual, direct, and substantial competition between Prestige and Insight and reducing the number of significant competitors in the market for OTC motion sickness medications, thereby increasing the likelihood that: (1) Prestige would be able to unilaterally

Order to Maintain Assets

exercise market power in this market; and (2) customers would be forced to pay higher prices.

VII. VIOLATIONS CHARGED

10. The Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

11. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-seventh day of August, 2014 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 Prestige Brands Holdings, Inc. (“Prestige”) of the voting securities of Respondent Insight Pharmaceuticals Corporation (“Insight”), 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

Order to Maintain Assets

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 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 Prestige is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 660 White Plains Road, Suite 250, Tarrytown, New York 10591.
2. Respondent Insight is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 900 Northbrook Drive, Suite 200, Trevose, Pennsylvania 19053.
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 and effective, the Decision and Order), which

Order to Maintain Assets

are incorporated herein by reference and made a part hereof, shall apply:

- A. “Prestige” means: Prestige Brands Holdings, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Prestige Brands Holdings, Inc. (including, without limitation, Medtech Products Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Prestige shall include Insight.
- B. “Insight” means: Insight Pharmaceuticals Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Insight Pharmaceuticals Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” means Prestige and Insight, individually and collectively.
- D. “Commission” means the Federal Trade Commission.
- E. “Decision and Order” means the:
 - 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 - 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- F. “Bonine Business” means the Business of Respondent Insight within the Geographic Territory specified in

Order to Maintain Assets

the Decision and Order related to Bonine to the extent that such Business is owned, controlled, or managed by Respondent Insight and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondent Insight.

- G. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- H. “Orders” means the Decision and Order and this Order to Maintain Assets.

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondents fully transfer and deliver the Bonine Assets to an Acquirer, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of the Bonine Business, to minimize any risk of loss of competitive potential for such Bonine Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Bonine Assets except for ordinary wear and tear. Respondents shall not sell, transfer, encumber or otherwise impair the Bonine Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the Bonine Business.
- B. Until Respondents fully transfer and deliver the Bonine Assets to an Acquirer, Respondents shall maintain the operations of the Bonine Business in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such Business) and/or as may be necessary to preserve the full economic marketability, viability, and competitiveness of the

Order to Maintain Assets

Bonine Business and shall use their best efforts to preserve the existing relationships with the following: manufacturers; suppliers; vendors and distributors; High Volume Accounts; end-use customers; Agencies; employees; and others having business relations with the Bonine Business. Respondents' responsibilities shall include, but are not limited to, the following:

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

Order to Maintain Assets

6. providing such support services to the Bonine Business as were being provided to such Business by Respondents as of the date the Consent Agreement was signed by Respondents;
7. developing and implementing a detailed transition plan to ensure that the commencement of the marketing, distribution and sale of Bonine by the Acquirer is not delayed or impaired by the Respondents for the purposes of ensuring and orderly marketing and distribution transition to the Acquirer;
8. designating employees of Respondents knowledgeable about the marketing, distribution and sale related to Bonine who will be responsible for communicating directly with the Acquirer, and the Interim Monitor (if one has been appointed), for the purposes of assisting in the transfer of Bonine;
9. maintaining and managing inventory levels of Bonine in consideration of the marketing and distribution transition to the Acquirer;
10. continuing to market, distribute and sell Bonine until such time as agreed upon with the Acquirer for the Acquirer to assume these functions, including, continuing, at their scheduled pace, any meetings with customers of the Bonine Business (such as, meetings to review planograms or displays, discuss marketing strategies, product promotions or product purchases);
11. allowing the Acquirer to access at reasonable business hours to all Confidential Business Information related to Bonine and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to Bonine that contain such Confidential Business Information pending the

Order to Maintain Assets

completed delivery of such Confidential Business Information to the Acquirer;

12. providing the Acquirer with a listing of inventory levels (week of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler or distributor) in a timely manner;
 13. providing the Acquirer with anticipated reorder dates for each customer in a timely manner; and
 14. establishing projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the Acquirer in an efficient and timely manner.
- C. Until Respondents fully transfer and deliver the Bonine Assets to an Acquirer, Respondents shall maintain a work force that is (i) at least as large (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with Bonine for the last fiscal year.
- D. Pending divestiture of the Bonine Assets, Respondents shall:
1. not use, directly or indirectly, any Confidential Business other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to the Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
 2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer, (ii) other Persons specifically authorized by such Acquirer to receive

Order to Maintain Assets

such information, (iii) the Commission, or (iv) the Interim Monitor (if any has been appointed);

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

Order to Maintain Assets

implemented and is being complied with. Respondents shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

- G. Respondents shall monitor the implementation by its employees and other personnel of all applicable restrictions with respect to Confidential Business Information, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets.
- H. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Bonine Business within the Geographic Territory through its full transfer and delivery to an Acquirer, to minimize any risk of loss of competitive potential for the Bonine Business within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Bonine Assets except for ordinary wear and tear.

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

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Interim 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 a proposed Interim Monitor within ten (10) days after notice by the staff of the

Order to Maintain Assets

Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.

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

provided, however, that, the Interim Monitor's service shall not exceed five (5) years from the Order Date unless the Commission decides to extend or modify

Order to Maintain Assets

this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
- F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

Order to Maintain Assets

- H. Respondents shall report to the Interim Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by each Acquirer with respect to the performance of Respondents' obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Orders; *provided, however,* beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph VII.B. of the Decision and Order, and ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward any necessary approvals to manufacture Bonine and obtaining the ability to manufacture Bonine in commercial quantities, in a manner consistent with cGMP, independently of Respondents.
- I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the

Order to Maintain Assets

Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

- L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The Interim Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondents have fully complied with this Order to Maintain Assets and the Paragraphs that are enumerated in Paragraph VII.B. of the related Decision and Order, 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 the Orders. Respondents shall submit at the same time a copy of their report concerning compliance with the Orders to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a detailed description of their efforts to comply with the relevant paragraphs of the Orders, including:

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

Order to Maintain Assets

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

V.

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

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

VI.

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

- A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized

Decision and Order

representative(s) of the Commission and at the expense of the Respondent; and

- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the later of:

- 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 divestiture of all of the Bonine Assets, as required by and described in the Decision and Order, has been completed and the Interim Monitor (if one has been appointed), in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to such divestitures are complete, or the Commission otherwise directs that this Order to Maintain Assets is terminated.

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Prestige Brands Holdings, Inc. (“Prestige”) of the voting securities of Respondent Insight Pharmaceuticals Corporation (“Insight”), collectively “Respondents”, and Respondents having been furnished thereafter with a copy of a

Decision and Order

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 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, 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 Prestige is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 660 White Plains Road, Suite 250, Tarrytown, New York 10591.
2. Respondent Insight is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 900 Northbrook Drive, Suite 200, Trevose, Pennsylvania 19053.

Decision and Order

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 the Order, the following definitions shall apply:

- A. “Prestige” means: Prestige Brands Holdings, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Prestige Brands Holdings, Inc. (including, without limitation, Medtech Products Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Prestige shall include Insight.
- B. “Insight” means: Insight Pharmaceuticals Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Insight Pharmaceuticals Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” means Prestige and Insight, individually and collectively.
- D. “Commission” means the Federal Trade Commission.
- E. “Acquirer(s)” means the following:
 1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent(s) is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order

Decision and Order

and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective; or

2. a Person approved by the Commission to acquire particular assets or rights that a Respondent(s) is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. "Acquisition" means Respondent Prestige's acquisition of fifty percent (50%) or more of the voting securities of Insight. Respondents entered into a *Stock Purchase Agreement* on April 25, 2014, to effect the Acquisition, by and among Medtech Products Inc. (a subsidiary of Prestige), Insight Pharmaceuticals Corporation, SPC Partners IV, L.P., and other shareholders in Insight that was submitted to the Commission.
- G. "Acquisition Date" means the date on which the Acquisition is consummated.
- H. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").
- I. "Application(s)" means all of the following: "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between a Respondent

Decision and Order

and the FDA related thereto. The term “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between a Respondent and the FDA related thereto.

- J. “Bonine” means all of the over-the-counter Products that contain the active pharmaceutical ingredient generically known as meclizine hydrochloride in Development, manufactured, marketed, sold, owned or controlled by Respondent Insight. “Bonine” includes, without limitation, all Products marketed or sold under the trademark Bonine®.
- K. “Bonine Assets” means the following assets and rights of Respondent Insight, as such assets and rights are in existence as of the date Respondent Insight signs the Agreement Containing Consent Orders in this matter and as are maintained by Respondent Insight in accordance with the Asset Maintenance Order until the Closing Date:
1. all rights to all of the Applications related to Bonine;
 2. all Product Intellectual Property related to Bonine that is not Product Licensed Intellectual Property;
 3. all Product Approvals related to Bonine;
 4. all Product Manufacturing Technology related to Bonine that is not Product Licensed Intellectual Property;
 5. all Product Marketing Materials related to Bonine;
 6. all Product Scientific and Regulatory Material related to Bonine;

Decision and Order

7. all Website(s) related exclusively to Bonine;
8. the content related exclusively to Bonine that is displayed on any Website that is not dedicated exclusively to Bonine;
9. a list of all of the NDC Numbers related to Bonine, and rights, to the extent permitted by Law:
 - a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of Bonine *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;
 - b. to prohibit Respondents from seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law;
 - c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the Respondents of any such cross-referencing that is discovered by Respondent);
 - d. to seek cross-referencing from a customer of the Respondent's NDC Numbers related to Bonine with the Acquirer's NDC Numbers related to Bonine;
 - e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of Bonine *except* for returns,

Decision and Order

rebates, allowances, and adjustments for Bonine sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement; and

- f. to approve any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondents prior to such notification(s) being disseminated to the customer(s);
- 10. all Product Development Reports related to Bonine;
 - 11. at the option of the Acquirer of Bonine, all Product Assumed Contracts related to Bonine (copies to be provided to the Acquirer on or before the Closing Date);
 - 12. a list of all customers and targeted customers for Bonine and a listing of the net sales (in either units or dollars) of Bonine to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of Bonine on behalf of the High Volume Account and his or her business contact information;
 - 13. at the option of the Acquirer of Bonine and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to Bonine;
 - 14. copies of all unfilled customer purchase orders for Bonine as of the Closing Date, to be provided to

Decision and Order

the Acquirer of Bonine not later than five (5) days after the Closing Date;

15. at the option of the Acquirer of Bonine, all unfilled customer purchase orders for Bonine; and

16. all of the Respondent's books, records, and files directly related to the foregoing;

provided, however, that "Bonine Assets" shall not include: (i) documents relating to any Respondent's general business strategies or practices relating to the conduct of its Business of marketing over-the-counter pharmaceutical Products, where such documents do not discuss with particularity Bonine; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of Bonine by the Interim Monitor or the Acquirer of Bonine; (v) any real estate and the buildings and other permanent structures located on such real estate; and (vi) all Product Licensed Intellectual Property;

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

Decision and Order

of information that, in content, also relates to Retained Product(s).

- L. “Bonine Divestiture Agreements” means the *Asset Purchase Agreement* between Wellspring Pharmaceutical Corporation and Medtech Products Inc. (an indirect subsidiary of Prestige Brands Holdings, Inc.) dated as of August 14, 2014; and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Bonine Assets that have been approved by the Commission to accomplish the requirements of this Order. The Bonine Divestiture Agreements are contained in Non-Public Appendix I.
- M. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement and sale of a Product.
- N. “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.
- O. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- P. “Closing Date” means the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Bonine Assets to the Acquirer pursuant to this Order.
- Q. “Confidential Business Information” means all information owned by, or in the possession or control of, any Respondent that is not in the public domain and

Decision and Order

that is directly related to the conduct of the Business related to Bonine. The term “Confidential Business Information” *excludes* the following:

1. information relating to any Respondent’s general business strategies or practices that does not discuss with particularity Bonine;
 2. information specifically excluded from the Bonine Assets;
 3. information that is contained in documents, records or books of any Respondent that is provided to the Acquirer by a Respondent that is unrelated to Bonine or that is exclusively related to Retained Product(s); and
 4. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.
- R. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- S. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the

Decision and Order

extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of a Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee;

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

- T. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondent Insight:
1. to research and Develop Bonine for marketing, distribution or sale within the Geographic Territory;
 2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell Bonine within the Geographic Territory;
 3. to import or export Bonine to or from the Geographic Territory to the extent related to the marketing, distribution or sale of Bonine in the Geographic Territory; and
 4. to have Bonine made anywhere in the World for distribution or sale within, or import into the Geographic Territory;

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

Decision and Order

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

- U. “Divestiture Product Releasee(s)” means the following Persons:
1. the Acquirer for the Bonine Assets;
 2. any Person controlled by or under common control with the Acquirer; and
 3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of the Acquirer, or of such Acquirer-affiliated entities.
- V. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- W. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- X. “Dramamine” means all Products Developed, marketed, sold, owned, or controlled by the Respondents under the trade name Dramamine®.
- Y. “Geographic Territory” shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.
- Z. “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.

Decision and Order

- AA. “High Volume Account(s)” means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of Bonine in the United States of America from Respondent Insight was, or is projected to be among the top twenty highest of such purchase amounts by Respondent Insight’s U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the Bonine Assets; or (iv) the end of the last quarter following the Acquisition or the Closing Date.
- BB. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- CC. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- DD. “Manufacturing Designee” means any Person other than a Respondent that has been designated by the Acquirer to manufacture Bonine for the Acquirer.
- EE. “NDC Number(s)” means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.
- FF. “Orders” means this Decision and Order and the related Order to Maintain Assets.
- GG. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.

Decision and Order

- HH. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- II. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- JJ. “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.
- KK. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- LL. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application related to that Product.

Decision and Order

- MM. “Product Assumed Contracts” means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):
1. that make specific reference to Bonine and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, Bonine from Respondent Insight unless such contract applies generally to Respondent Insight’s sales of Products to that Third Party;
 2. pursuant to which Respondent Insight had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in connection with the manufacture of Bonine;
 3. relating to any Clinical Trials involving Bonine;
 4. with universities or other research institutions for the use of Bonine in scientific research;
 5. relating to the particularized marketing of Bonine or educational matters relating solely to Bonine(s);
 6. pursuant to which a Third Party manufactures Bonine on behalf of Respondent Insight;
 7. pursuant to which a Third Party provides any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of Bonine on behalf of Respondent;
 8. pursuant to which a Third Party provides the Product Manufacturing Technology related to Bonine to Respondent Insight;

Decision and Order

9. pursuant to which a Third Party is licensed by Respondent Insight to use the Product Manufacturing Technology;
10. constituting confidentiality agreements involving Bonine;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving Bonine;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of Bonine to Respondent Insight including, but not limited to, consultation arrangements; and/or
13. pursuant to which any Third Party collaborates with Respondent Insight in the performance of research, Development, marketing, distribution or selling of Bonine or the Business related to Bonine;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), Respondent Insight shall assign the Acquirer all such rights under the contract or agreement as are related to Bonine, but concurrently may retain similar rights for the purposes of the Retained Product(s).

- NN. “Product Copyrights” means rights to all original works of authorship of any kind directly related to Bonine and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing or sale of that Product, including all

Decision and Order

copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product's sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of a Respondent who accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

OO. "Product Development Reports" means:

1. Pharmacokinetic study reports related to Bonine;
2. Bioavailability study reports (including reference listed drug information) related to Bonine;
3. Bioequivalence study reports (including reference listed drug information) related to Bonine;
4. all correspondence, submissions, notifications, communications, registrations or other filings

Decision and Order

made to, received from or otherwise conducted with the FDA relating to the Application(s) related to Bonine;

5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to Bonine;
7. currently used or planned product package inserts (including historical change of controls summaries) related to Bonine;
8. FDA approved patient circulars and information related to Bonine;
9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to Bonine;
10. summary of Product complaints from physicians related to Bonine;
11. summary of Product complaints from customers related to Bonine;
12. Product recall reports filed with the FDA related to Bonine, and all reports, studies and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in Bonine;
14. reports related to Bonine from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;

Decision and Order

15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce Bonine that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of Bonine;
 16. analytical methods development records related to Bonine;
 17. manufacturing batch records related to Bonine;
 18. stability testing records related to Bonine;
 19. change in control history related to Bonine; and
 20. executed validation and qualification protocols and reports related to Bonine.
- PP. “Product Intellectual Property” means all of the following related to Bonine (other than Product Licensed Intellectual Property):
1. Patents;
 2. Product Copyrights;
 3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
 4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;
- provided, however*, “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Prestige” or “Insight” or the related

Decision and Order

corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondents or the related corporate logos thereof, or general registered images or symbols by which Prestige, or Insight can be identified or defined.

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

1. Patents that are related to Bonine that the Respondents can demonstrate have been used, prior to the Acquisition Date, for any Retained Product; and
2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to Bonine and that the Respondents can demonstrate have been used, prior to the Acquisition Date, for any Retained Product.

RR. “Product Manufacturing Technology” means all of the following related to Bonine:

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

Decision and Order

Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;

2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients or packaging materials; and,
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture that Product.

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

TT. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information.

UU. "Product Trade Dress" means the current trade dress of a Product, including but not limited to, Product

Decision and Order

packaging, and the lettering of the Product trade name or brand name.

- VV. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.
- WW. “Remedial Agreement(s)” means the following:
1. any agreement between a Respondent(s) and the Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;
 2. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to Bonine to the benefit of the Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;
 3. any agreement between a Respondent(s) and the Acquirer (or between a Divestiture Trustee and the Acquirer) that has been approved by the

Decision and Order

Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by that Respondent(s) to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or

4. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to Bonine to the benefit of the Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

XX. “Retained Product” means any Product(s) other than Bonine.

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

1. designating employees of the Respondent(s) knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to Bonine who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;

Decision and Order

2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to Bonine that are acceptable to the Acquirer;
 3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and
 4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
 - a. manufacture Bonine in the quality and quantities achieved by the Respondent Insight, or the manufacturer Bonine on behalf of Respondent Insight;
 - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell Bonine in commercial quantities and to meet all Agency-approved specifications for Bonine; and
 - c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to Bonine.
- ZZ. “Third Party(ies)” means any non-governmental Person other than the following: the Respondents; or, the Acquirer of particular assets or rights pursuant to this Order.
- AAA. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by

Decision and Order

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

BBB. “Wellspring” means Wellspring Pharmaceutical Corporation, a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 5911 North Honore Avenue, Suite 211, Sarasota, Florida 34243.

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

- A. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondents shall divest the Bonine Assets and grant the related Divestiture Product License, absolutely and in good faith, to Wellspring pursuant to, and in accordance with, the Bonine Divestiture Agreement(s) (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Wellspring or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Bonine Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Bonine Assets to Wellspring prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Wellspring is not an acceptable purchaser of the Bonine Assets, then

Decision and Order

Respondents shall immediately rescind the transaction with Wellspring, in whole or in part, as directed by the Commission, and shall divest the Bonine Assets within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondents have divested the Bonine Assets to Wellspring prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, 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 Bonine Assets to Wellspring (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 assets required to be divested pursuant to this Order to the Acquirer, and to permit the Acquirer to continue the Business of Bonine;

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:
1. submit to the Acquirer, at Respondents' expense, all Confidential Business Information;
 2. deliver all Confidential Business Information to the Acquirer:

Decision and Order

- a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to the Acquirer, provide the Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to Bonine that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any such Confidential Business Information related to the Business of Bonine other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to the Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer, (ii) other Persons specifically authorized by the Acquirer to receive such information, (iii) the Commission, or (iv) the Interim Monitor (if any has been appointed); and
6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business

Decision and Order

Information related to the marketing or sales of Bonine to the marketing or sales employees associated with the Business related to the Retained Product Dramamine.

- D. Respondents shall provide, or cause to be provided to the Acquirer in a manner consistent with the Technology Transfer Standards the following:
1. all Product Manufacturing Technology (including all related intellectual property) related to Bonine; and
 2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to any Respondent related to Bonine.

Respondents shall obtain any consents from Third Parties required to comply with this provision. No Respondent shall 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 use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to Bonine. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the Product 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 the Acquirer.

- E. Respondents shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had responsibilities related to the marketing or

Decision and Order

sales of Bonine within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of the Retained Product Dramamine, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to Bonine as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).

- F. Not later than thirty (30) days after the Closing Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to Bonine by Respondents' personnel to all of their employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondents shall provide a copy of the notification to the Acquirer. Respondents shall maintain complete records of all such notifications at Respondents' principal business office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondents shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.
- G. Until Respondents complete the divestitures required by this Order and fully provide, or cause to be provided, the Product Manufacturing Technology related to a particular Bonine to the Acquirer,

Decision and Order

1. Respondents shall take actions as are necessary to:
 - a. maintain the full economic viability and marketability of the Businesses associated with Bonine;
 - b. minimize any risk of loss of competitive potential for that Business;
 - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to Bonine;
 - d. ensure that the Bonine Assets are provided to the Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with Bonine; and
 - e. ensure the completeness of the transfer and delivery of such Product Manufacturing Technology; and
 2. Respondents shall not sell, transfer, encumber or otherwise impair the Bonine Assets (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses associated with Bonine.
- H. From the Closing Date, Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Acquirer or the Divestiture Product Releasee(s) of the Acquirer under the following:
1. any Patent owned by or licensed to a Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

Decision and Order

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

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

- I. Upon reasonable written notice and request from the Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist the Acquirer to defend against,

Decision and Order

respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to Bonine, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of Bonine for the purposes of marketing, sale or offer for sale within the United States of America of Bonine; or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of Bonine.

- J. For any patent infringement suit filed prior to the Closing Date in which any Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that any Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of Bonine for the purposes of marketing, sale or offer for sale within the United States of America of Bonine; or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of Bonine, that Respondent shall:
1. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to Bonine;
 2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent the Acquirer in any ongoing patent litigation related to Bonine; and
 3. permit the transfer to the Acquirer of all of the litigation files and any related attorney work-

Decision and Order

product in the possession of that Respondent's outside counsel related to Bonine.

- K. The purpose of the divestiture of the Bonine Assets and the provision of the related Product Manufacturing Technology and the related obligations imposed on the Respondents by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business associated with Bonine within the Geographic Territory; and
 2. to create a viable and effective competitor that is independent of Respondents in the Business of Bonine within the Geographic Territory; and,
 3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

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

- A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that the Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.
- B. The Commission shall select the Interim 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 a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be

Decision and Order

deemed to have consented to the selection of the proposed Interim Monitor.

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

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

Decision and Order

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with its obligations under the Orders, including, but not limited to, its obligations related to the Bonine Assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
- F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
- H. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the

Decision and Order

reports submitted to the Interim Monitor by Respondents, and any reports submitted by each Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order; *provided, however*, beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph VII.B., and ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by each Acquirer toward obtaining any necessary approvals to manufacture Bonine and obtaining the ability to manufacture Bonine in commercial quantities, in a manner consistent with cGMP, independently of Respondents.

- I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional

Decision and Order

orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.

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

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

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Bonine Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*I*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*I*), 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(*I*) 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

Decision and Order

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, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
 - 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

Decision and Order

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to the Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary

Decision and Order

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

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

Decision and Order

relevant provisions of this Order or the Order to Maintain Assets in this matter.

8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
 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*, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, each Respondent shall assure that its

Decision and Order

own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to the Acquirer or access original documents provided to the Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

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

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

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

Decision and Order

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

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. 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 each Respondent's obligation to the Acquirer pursuant to this Order.
- D. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to Bonine a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- E. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

Decision and Order

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

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with Paragraphs II.A., II.B., II.C.1.-3., II.D., II.E., and II.G., Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondents shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:
 - 1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, and (ii) transitional services being provided by the Respondents to the Acquirer; and
 - 2. a detailed description of the timing for the completion of such obligations.
- C. One (1) year after the Order Date, annually for the next nine (9) years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

Decision and Order

VIII.

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

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

IX.

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

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

Analysis to Aid Public Comment

X.

IT IS FURTHER ORDERED that this Order shall terminate on October 7, 2024.

By the Commission.

NON-PUBLIC APPENDIX I**AGREEMENTS RELATED TO THE DIVESTITURE**

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

**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 Prestige Brands Holdings, Inc. (“Prestige”) and Insight Pharmaceuticals Corporation (“Insight”), which is designed to remedy the anticompetitive effects of Prestige’s acquisition of Insight.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the

Analysis to Aid Public Comment

Commission will again evaluate the proposed Consent Agreement, along with the comments received, in order to make a final decision as to whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Pursuant to a Stock Purchase Agreement dated April 25, 2014, Medtech Products Inc. (“Medtech”), a subsidiary of Prestige, intends to purchase all of the outstanding shares of Insight for approximately \$750 million (the “Proposed Acquisition”). Both parties sell over-the-counter (“OTC”) motion sickness medications in the United States. The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening competition in U.S. markets for the manufacture, marketing, distribution, and sale of OTC motion sickness medications. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition. Specifically, under the terms of the Consent Agreement, Prestige would be required to divest all of Insight’s rights and assets related to its OTC motion sickness product, Bonine. Prestige has proposed Wellspring Pharmaceutical Corporation (“Wellspring”) as the buyer of the assets.

II. The Product and Structure of the Market

Prestige’s proposed acquisition of Insight would significantly increase concentration in the OTC motion sickness medications market. Motion sickness is a condition in which a disagreement exists between visually perceived movement and the balance center of the inner ear’s sense of movement. For example, a passenger on a ship might experience motion sickness if the inner ear senses the motion of waves, but the passenger’s eyes do not see any movement. The most common symptoms of motion sickness are dizziness, fatigue, and nausea.

Prestige markets and sells the bestselling brand of OTC motion sickness medication, Dramamine. The only other branded OTC motion sickness medication with significant sales

Analysis to Aid Public Comment

is Bonine, which is sold and marketed by Insight. Alva-Amco sells the only other branded OTC motion sickness medication, but its sales are minimal. Private label OTC motion sickness products have significant sales, but private label OTC products have only a limited competitive impact in the market because they are usually priced at a fixed discount to branded OTC motion sickness medication products. Plus, private label products are not typically promoted or marketed. Unremedied, the Proposed Acquisition will consolidate the two most significant suppliers of OTC motion sickness medications and would substantially increase the Herfindahl-Hirschman Index.

III. Entry

Entry into the manufacture and sale of OTC motion sickness medications would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. The high up-front costs associated with establishing a reputable and competitive brand are significant when compared to the limited sales available in the United States. This high cost of entry relative to sales opportunities is exacerbated by the difficulty a new entrant would have in convincing retailers to either add a new untested brand to shelves or supplant an existing brand with its new brand.

IV. Effects

The Proposed Acquisition would likely cause significant anticompetitive harm to consumers in the market for the manufacture and sale of OTC motion sickness medications by eliminating actual, direct, and substantial competition between Prestige and Insight in this market. The Proposed Acquisition would likely result in higher prices for consumers because it would remove the close competition between Prestige's Dramamine and Insight's Bonine in terms of pricing and promotional activities.

V. The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant

Analysis to Aid Public Comment

market. Pursuant to the Consent Agreement, the parties are required to divest Insight's rights and assets related to Bonine to WellSpring. Further, the proposed Consent Agreement requires Insight to assign to WellSpring its contract manufacturing and contract packaging agreements for the divested assets. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the Proposed Acquisition is consummated.

WellSpring is well-suited to acquire the Bonine assets because of its current presence in other OTC retail markets. WellSpring produces and markets a portfolio of OTC brands, including anti-nausea products, skin creams, hygiene products, and potassium supplements, which are widely distributed throughout the United States and Canada. In addition, WellSpring is a contract manufacturing organization serving well-known U.S. pharmaceutical companies while also manufacturing many of its own products at its plant in Oakville, Ontario, Canada. Since WellSpring will step into Insight's existing contract manufacturing relationship for the production of Bonine, no transfer of manufacturing will be necessary for the proposed divestiture and WellSpring will be able to compete immediately in the OTC motion sickness medications market.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that WellSpring is not an acceptable acquirer of the divested assets, or that the manner of the divestiture is not acceptable, the parties must unwind the sale of rights to WellSpring, and divest the Bonine assets to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the product if the parties fail to divest it as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestiture is successful. The Order requires Prestige and Insight to take all action necessary to maintain the economic viability, marketability, and competitiveness of the product to be divested until such time that they are transferred to a Commission-approved acquirer. The

Analysis to Aid Public Comment

Order also requires that Prestige and Insight transfer all confidential business information, including customer information related to the divestiture product, to Wellspring.

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

Complaint

IN THE MATTER OF

JOHN MATTHEW DWYER III**A/K/A****MATTHEW DWYER**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4492; File No. 122 3287**Complaint, October 22, 2014 – Decision, October 22, 2014*

This consent order addresses John Matthew Dwyer III's advertising for HealthyLife Sciences, LLC's Healthe Trim line of weight loss dietary supplements ("Healthe Trim"). The complaint alleges that Dwyer, a co-founder of HealthyLife Sciences, LLC, and former chief executive officer and spokesman for Healthe Trim, violated Sections 5(a) and 12 of the Federal Trade Commission Act by making false or unsubstantiated representations that Healthe Trim would cause rapid and substantial weight loss, including as much as 35, 130, and 165 pounds. The consent order bans Dwyer from manufacturing, marketing, or distributing any weight-loss product or program, or assisting others in any of the foregoing. The order also prohibits any representation about the health benefits, performance, or efficacy of any dietary supplement, food, or drug, unless it is non-misleading and supported by competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

Participants

For the *Commission*: Christine DeLorme and Elizabeth Nach.

For the *Respondent*: John Matthew Dwyer III, *pro se*.

COMPLAINT

The Federal Trade Commission, having reason to believe John Matthew Dwyer III, individually ("Respondent"), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent John Matthew Dwyer III, a/k/a Matthew Dwyer ("Dwyer"), is the co-founder of HealthyLife Sciences,