

UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION

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

	)		
In the Matter of	)		
	)		
LUPIN LTD,	)		Docket C-4566
	)		
NOVEL LABORATORIES, INC.,	)		
a corporation.	)		
	)		

**ORDER TO MAINTAIN ASSETS**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Lupin Ltd. (“Lupin”) of the voting securities of Respondent Gavis Pharmaceuticals LLC (“Gavis”) and Respondent Novel Laboratories, Inc. (“Novel”), 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 not constitute an adm

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 Lupin i

“Gavis” means:

## **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 each of the respective Divestiture Product Assets to

4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products that were marketed or sold by Respondents prior to the date the Respondents entered the agreement to effect the Acquisition (as such agreement is identified in the definition of Acquisition), at the related High Volume Accounts;
  5. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such Divestiture Product Business; and
  6. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such Divestiture Product Business by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. For the Acquirer of Doxycycline, Respondents shall:
1. for a period of twelve (12) months from the Closing Date or until the hiring of twenty (20) Doxycycline Core Employees by that Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Doxycycline Core Employees related to the Doxycycline Assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Doxycycline Core Employee Access Period;"
  2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondents to provide the Doxycycline Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer with the Doxycycline Employee Information related to the Doxycycline Core Employees. Failure by Respondents to provide the Doxycycline Employee Information for any Doxycycline Core Employee within the time provided herein shall extend the Doxycycline Core Employee Access Period with respect to that employee in an amount equal to the delay; provided, however, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide, or providing, to Doxycycline Core Employees the opportunity to enter into employment contracts during a Doxycycline Core Employee Access Period, and (iii) restrict access to the information to

such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use;

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

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

4. until the Closing Date, provide all Doxycycline Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Doxycycline Product consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Doxycycline Assets and to ensure successful execution of the pre-Acquisition plans for Doxycycline. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date for the divestiture of the assets related to the Doxycycline has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law); and

provided, however, that this Paragraph does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Doxycycline Core Employees in connection with the Acquisition;

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

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

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

- E. During the Transition Period, with respect to each Doxycycline Product that is marketed or sold in the United States before the Closing Date, Respondents, in consultation with the Acquirer, for the purposes of ensuring an orderly marketing and distribution transition, shall:
1. develop and implement a detailed transition plan to ensure that the commencement of the marketing, distribution, and sale of such Doxycycline Products by the Acquirer is not delayed or impaired by the Respondents;
  2. designate employees of Respondents knowledgeable about the marketing, distribution and sale of each of the Doxycycline Products who will be responsible for communicating directly with the Acquirer, and the Monitor (if one has been appointed), for the purposes of assisting in the transfer of the Divestiture Products Business to the Acquirer;
  3. maintain and manage inventory levels of the Doxycycline Products in consideration of the marketing and distribution transition to the Acquirer;
  4. continue to market, distribute, and sell the Doxycycline Products;
  5. allow the Acquirer access at reasonable business hours to all Confidential Business Information related to the Doxycycline Products and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products that contain such Confidential Business Information pending the completed delivery of such Confidential Business Information to the Acquirer;
  6. provide the Acquirer with a listing of inventory levels (week of supply) for each customer (i.e., retailer, group purchasing organization, wholesaler, or distributor) on a regular basis and in a timely manner;

7. provide the Acquirer with anticipated reorder dates for each customer on a regular basis and in a timely manner; and
8. establish projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the Acquirer in an efficient and timely manner.

F. Pending divestiture of the Divestiture Product Assets, Respondents shall:

1. not use, directly or indirectly, any Confidential Business Information related to the Divestiture Products Business other than as necessary to comply with the following:
  - a. the requirements of this Order;
  - b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
  - c. applicable Law;
2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Assets, (ii) other Persons specifically authorized by such Acquirer to receive such information (e.g., employees of the Respondent responsible for the Contract Manufacture of a Divestiture Product on behalf of an Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed);
3. not provide, disclose, or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Divestiture Products to the employees associated with the Business related to those Retained Products that are the therapeutic equivalent (as that term is defined by the FDA) of the Divestiture Products; and
4. institute procedures and requirements to ensure that the above-described employees:
  - a. do not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
  - b. do not solicit, access, or use any Confidential Business Information that they are prohibited from receiving for any reason or purpose.



- G. Not later than thirty (30) days 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 related to the Divestiture Products 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.
- H. 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 affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications, and reminders sent to Respondents' personnel.
- I. 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.
- J. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability, and competitiveness of the Divestiture Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer, to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Product Assets except for ordinary wear and tear.

### **III.**

#### **IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("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. The Commission hereby appoints Francis J. Civile as the Monitor and approves the Monitor Agreements between Mr. Civile and Respondents.
- B. The Commission shall select the Monitor, subject to the consent of Respondents, which consent

- C. Not later than ten (10) days after the appointment of the Monitor, Respondents shall execute one or more agreement(s) that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondents' compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The 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 Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
  2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
  3. The Monitor shall serve until the date of completion by the Respondents of the divestiture of all Divestiture Product Assets and, with respect to the Doxycycline Assets, the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order until the earliest of: (i) date the Acquirer of the Doxycycline Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture the Doxycycline Product and is able to manufacture the Doxycycline Product in commercial quantities, in a manner consistent with cGMP, independently of the Respondents; (ii) the date the Acquirer of the Doxycycline Product notifies the Commission and Respondents of its intention to abandon its efforts to manufacture the Doxycycline Product; or (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture the Doxycycline Product;
- provided, however, that, with respect to the Doxycycline Product, the Monitor's service shall not extend more than five (5) years after the Order Date unless the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.
- E. Subject to any demonstrated legally recognized privilege, the 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 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 Monitor and shall take no action

to interfere wit

- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The 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 IX.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 Monitor, if any 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, (ii) transitional services being provided by the Respondents to the relevant Acquirer(s), and (iii) the agreement(s) to Contract Manufacture; and
- B. a detailed description of the timing for the completion of such obligations;

- 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 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 Divestiture Product Assets, as required by and described in the Decision and Order, has been completed; or

- C. the day after the Product Manufacturing Technology related to each Divestiture Product that is a Contract Manufacture Product has been provided to the Acquirer in a manner consistent with the Technology Transfer Standards and the Monitor, in consultation with Commission staff and the Acquirer, notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers, and other transitions related to the provision of the Product Manufacturing Technology are complete; or
- D. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

Donald S. Clark  
Secretary

SEAL:  
ISSUED: February 18, 2016