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**UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION**

**COMMISSIONERS:      Jon Leib**

Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent Valent is a corporation organized, existing and doing business under and by virtue of the laws of Canada, with its corporate head office and principal place of business located at 7150 Mississauga Road, Mississauga, Ontario L5N 8M5, Canada.
2. Sanofi is a corporation organized, existing and doing business under and by virtue of the laws of the French Republic, with its global headquarters located at 174 Avenue de France, 75013 Paris, France and the address of its United States subsidiary Sanofi-Aventis US LLC, located at 55 Corporate Drive, Bridgewater, New Jersey

- E. "Divestiture Product Business(es)" means the business of the Respondent within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products, including the research, Development, manufacture, distribution, marketing and sale of each Divestiture Product and the assets related to such business, including without limitation, the Divestiture Assets.
- F. "Divestiture Products" means the Clindamycin-Benzoyl Products and the Fluorouracil Products, individually and collectively, as defined in the Decision and Order
- G. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph II 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 Respondent fully transfers and delivers each of the respective Divestiture Assets to an Acquirer, Respondent shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting deterioration, or impairment of such Divestiture Product Businesses except for ordinary wear and tear. Respondent shall not sell, transfer, encumber or otherwise impair such Divestiture Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the related Divestiture Product Businesses.
- B. Until Respondent fully transfers and delivers each of the respective Divestiture Assets to an Acquirer, Respondent shall maintain the operations of the related Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the marketability, viability, and competitiveness of such Divestiture Product Businesses and shall use its best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; the High Volume Accounts; customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses. Respondent's responsibilities shall include, but are not limited to:
 

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respect to such business and transactions, at least to the extent of their scheduled pace all capital projects,

c. applicable Law;

2. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except the Acquirer of the Clindamycin-Benzoyl Peroxide Products or other Persons specifically authorized by that Acquirer to receive such information; and
3. not provide, disclose or otherwise make available directly or indirectly, any Confidential Business Information related to the marketing or sales of the the Clindamycin-Benzoyl Peroxide Products to the employees associated with businesses related to those Retained Products that contain these active pharmaceutical ingredient as the Clindamycin-Benzoyl Peroxide Products.

E. Not later than thirty (30) days from the earlier of the Closing Date or the date that this Order to Maintain Assets becomes final and effective, Respondent shall provide to all of Respondent's employees and other personnel who may have access to Confidential Business Information related to the Divestiture Products notification of the restrictions on the use of such information by Respondent's personnel. Respondent shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondent shall provide a copy of such notification to the Acquirer. Respondent shall maintain complete records of all such agreements at Respondent's registered office within the United States and shall provide chief officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondent shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

F. Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions, 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. Respondent shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondent's employees and other personnel.

G. During the term of any agreement to Contract Manufacture between the Respondent and a Acquirer, Respondent shall take

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 Assets except for ordinary wear and tear.

### III.

#### IT IS FURTHER ORDERED that:

- A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent promptly complies with all of its obligations and performs all of its responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
  1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
  2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
  3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of a Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:

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

*provided, however, that, with respect to the Fluorouracil Products, the Interim Monitor's services shall not exceed five (5) years from the Order Date;*

*provided, further, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.*

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

7. Respondent shall report to the Interim Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's 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 Respondent of its obligations under the Orders.
8. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. 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.
- F. 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 provided in this Paragraph.
- G. 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.
- H. The Interim Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Destitute 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 becomes final and effective, and every thirty (30) days thereafter until Respondent has fully complied with its obligations to assign, rent, license, divest, transfer, deliver or otherwise convey relevant assets as required by Paragraph I.A. and I.B. of the related Decision and Order in this matter, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, and has complied with this Order to Maintain Assets and the related Decision and Order; *provided, however, that*, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph VI of the Decision and Order.



V.

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

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

VI.

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

- A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence memoranda and all other records and documents in the possession or under the control of the Respondent related to compliance with this Order, while 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 earlier 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 later of:

1. The day after the divestiture of all of the Divestiture Assets, as required by and described in the Decision and Order has been completed and the Interim Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to such divestitures are complete, or the Commission otherwise directs that this Order to Maintain Assets is terminated; or
2. the day after the day the related Decision and Order becomes final and effective.

By the Commission.

Donald S. Clark  
Secretary

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ISSUED: December 9, 2011