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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **William E. Kovacic, Chairman**
Pamela Jones Harbour
Jon Leibowitz
J. Thomas Rosch

In the Matter of **FRESENIUS MEDICAL CARE AG & CO. KGaA,** **a German partnership,** **and** **DAIICHI SANKYO COMPANY, LTD. ,** **a Japanese corporation.**	**Docket No. C-**

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq*., and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Fresenius Medical Care AG & Co. KGaA ("Fresenius") and Daiichi Sankyo Company, Ltd. ("Daiichi"), have violated Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and, in addition, violated Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges in that respect as follows:

I. DEFINITIONEi(LdTD.0geiJ0 So)8.uNITIONEi(LdTD.0geiJ0 So)8.9

virtue of the laws of New York, with its office and principal place of business located at One Luitpold Drive, Shirley, New York 11967. American Regent, Inc., a wholly owned subsidiary of Luitpold Pharmaceuticals, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of New York, with its office and principal place of business located at One Luitpold Drive, Shirley, New York. 11967. Luitpold licences Venofer from Vifor (International) Inc. ("Vifor"), the Swiss pharmaceutical company that developed the product. Luitpold's subsidiary, American Regent, Inc. ("American Regent"), markets and distributes all of Luitpold's injectable products, including Venofer, to customers around the United States.

11. Respondents are, and at all times relevant herein have been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. §12, and are corporations whose business is in or affects commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED TRANSACTION

12. Pursuant to a License, Distribution, Manufacturing and Supply Agreement dated July 8, 2008, Luitpold and Vifor agreed to grant FMCUSA an exclusive sublicense to distribute, manufacture and sell Venofer to Independent Outpatient Dialysis Clinics in the United States for a term of ten years with an option to extend the agreement for an additional ten years (hereinafter "Proposed Transaction"). Luitpold retains the right to sell Venofer in the United States to any other customer, including doctor's offices, hospitals and hospital-based dialysis clinics.

IV. THE RELEVANT MARKET

13. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Proposed Transaction is the manufacture, distribution and sale of IV Iron. IV Iron is critical for the effective treatment of dialysis patients, the vast majority of whom suffer from chronic anemia.

14. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Proposed Transaction in the relevant line of commerce.

16. CMS reimburses Independent Outpatient Dialysis Clinics for the vast majority of the IV Iron used in the United States. Currently, CMS's reimbursement rate for Venofer is one hundred and six percent of the Manufacturers' Average Sales Price to all purchasers. Each calendar quarter, pursuant to Medicare Part B, drug manufacturers are required to submit the Manufacturers' Average Sales Price to CMS and that information is used to calculate the CMS reimbursement rate for each IV Iron product.

VI. ENTRY CONDITIONS

17. Entry into the relevant line of commerce described in Paragraphs 13 and 14 would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Transaction.

VII. EFFECTS OF THE PROPOSED TRANSACTION

18. The effects of the Proposed Transaction, if consummated, may be substantially to lessen competition and to 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 others, enabling Fresenius to report higher prices for Venofer used in its own clinics to CMS thereby increasing the Manufacturer's Average Sales Price and, therefore, the reimbursement rate for Venofer. By increasing the reimbursement rate for Venofer, CMS would be forced to pay higher prices for Venofer administered to dialysis patients covered by Medicare.

19. The effects described in Paragraph 18 would persist until the Bundled Payment System is fully implemented.

VIII. VIOLATIONS CHARGED

20. The Proposed Transaction described in Paragraph 12 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

21. The Proposed Transaction described in Paragraph 12, 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 _____ day of _____ issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: