

**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-4236**

**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. DEFINITIONS**

1. “IV Iron” means second-generation intravenous iron therapy products, including Venofer (iron sucrose) and Ferrlecit (sodium ferric gluconate).
2. “Independent Outpatient Dialysis Clinics” means facilities that provide dialysis services and that are not hospital-based facilities and do not meet all of the criteria set forth in 42 C.F.R. §413.174(c) (and any successor or amended regulations).

3. “Medicare Part B” means Section 1847A(b); 42 U.S.C. § 1395w-3a(c).
4. Manufacturers’ Average Sales Price has the same meaning as that in 42 U.S.C. § 1395w-3a(c).
5. “CMS” means Centers for Medicare & Medicaid Services of the United States Department of Health & Human Services.
6. “Respondents” means Fresenius and Daiichi, individually and collectively.
7. “Medicare Improvements for Patients and Providers Act of 2008” or “MIPPA,” means Public Law No. 110-275.
8. “Bundled Payment System” means the system created under Section 153(b) of the MIPPA whereby, among other things, reimbursement to providers of dialysis services for IV Iron administered to dialysis patients will be included in a single payment, and no longer billed separately, by January 1, 2015.

## II. RESPONDENTS

9. Fresenius Medical Care AG & Co. KGaA is a partnership limited by shares organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its offices and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany. Fresenius Medical Care AG & Co. KGaA is the parent of Fresenius Medical Care Holdings, Inc., a New York corporation, d/b/a Fresenius Medical Care North America (“FMCNA”) with its office and principal place of business located at 920 Winter St., Waltham, MA 023451-1457. Renal Therapies Group (“RTG”), a division of FMCNA , manufactures, sells and distributes equipment, supplies and pharmaceuticals to dialysis providers. RTG is the parent entity of FMC USA Manufacturing (“FMCUSA”), which is the Fresenius signatory to the Proposed Transaction.

10. Daiichi Sankyo Company, Ltd. is a corporation organized, existing and doing business under and by virtue of the laws of Japan, with its office and principal place of business located at 3-5-1, Nihonbashi Honcho, Chuo-Ku, Tokyo 103-8426, Japan. Daiichi Sankyo, Inc. (“DSI”), a wholly owned subsidiary of Daiichi Sankyo Company, Ltd., is a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at Two Hilton Court, Parsippany, New Jersey 07054. Luitpold Pharmaceuticals, Inc., a wholly owned subsidiary of DSI, 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. 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.

### **V. THE STRUCTURE OF THE MARKET**

15. The U.S. market for IV Iron is highly concentrated. Luitpold and Watson Pharmaceuticals (“Watson”) are the only two suppliers of IV Iron in the United States. Luitpold manufactures, distributes and sells Venofer, and Watson manufactures, distributes and sells Ferrlecit.

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 twentieth day of October, 2008, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark  
Secretary

SEAL: