



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

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 patients.