

Complaint

IN THE MATTER OF

**FRESENIUS MEDICAL CARE AG & CO. KGaA,
AND
DAIICHI SANKYO COMPANY, LTD.**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL
TRADE COMMISSION ACT

Docket C-4236; File No. 081 0146

Complaint, October 20, 2008 – Decision, October 20, 2008

This consent order relates to a proposed agreement between subsidiaries of Fresenius Medical Care and Daiichi Sankyo to grant an exclusive license to Fresenius subsidiary FMC USA Manufacturing to manufacture, distribute, and sell Venofer, a preparation used to treat dialysis patients, to independent outpatient dialysis clinics in the United States. Luitpold Pharmaceuticals, a subsidiary of Daiichi Sankyo, retains the right to sell Venofer in the United States to any other customer, including doctor's offices, hospitals and hospital-based dialysis clinics. The transaction may enable Fresenius to increase prices it charges its own clinics, which, in turn, would raise reimbursement rates that the Centers for Medicare & Medicaid Services pays for Venofer. Under the order, Fresenius is restricted from reporting an intra-company transfer price higher than the level set forth in the order, which is derived from current market prices. The order further provides that if a generic Venofer product receives final approval by the U.S. Food and Drug Administration, Fresenius would be required to report its intra-company transfer price at either the level set forth in the order or the lowest price at which Fresenius sells Venofer to any customer, whichever is lowest, until December 31, 2011. On January 1, 2012, the order removes the lowest-priced-customer restriction, while the level set forth in the order remains in place. The order also provides that if Medicare & Medicaid Services implements regulations that eliminate the potential anticompetitive harm of this transaction, those regulations will supersede the order. The order prohibits Luitpold and Fresenius from sharing confidential business information relating to the manufacture, sale, or distribution of Venofer, and requires the parties to provide notice to the Commission prior to modifying the license agreement. Finally, the order provides that the Commission may appoint a Monitor Trustee if necessary.

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Participants

For the *Commission*: Sylvia M. Brooks, Lisa De Marchi Sleigh, Daniel P. Ducore, David A. Garcia, Michael R. Moiseyev, Christina R. Perez, James E. Southworth, and Steven Tenn.

For the *Respondents*: Larri A. Short, Arent Fox LLP; Robert L. Magielnicki, Sheppard, Mullin, Richter & Hampton LLP; and Susan S. DeSanti and Katherine Funk, Sonnenschein Nath & Rosenthal LLP.

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).

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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 02345-1457. 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.

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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.

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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

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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

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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.

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed exclusive sublicense and manufacturing and supply agreement for Venofer, an intravenous iron drug used for the treatment of anemia, to free-standing outpatient dialysis clinics, between Fresenius Medical Care AG & Co. KGaA, a German partnership limited by shares, and including entities and divisions controlled by Fresenius Medical Care AG & Co. KGaA, including (1) Fresenius Medical Care Holdings, Inc., a New York corporation wholly owned by Fresenius Medical Care AG & Co. KGaA, d/b/a Fresenius Medical Care North America, (2) Fresenius Medical Services, which operates dialysis clinics throughout North America, (3) Renal Therapies Group, which manufactures, sells and distributes equipment, supplies and pharmaceuticals to dialysis providers, and (4) Renal Research Institute, which engages in dialysis research and development (hereafter collectively referred to as “Respondent Fresenius”) and Daiichi Sankyo Company, Ltd., a Japanese pharmaceutical company, and entities controlled by Daiichi Sankyo Company, Ltd., including (1) Daiichi Sankyo, Inc., a Delaware corporation, wholly owned by Daiichi Sankyo Company, Ltd., (2) Luitpold

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Pharmaceuticals, Inc., a New York corporation, wholly owned by Daiichi Sankyo, Inc., and (3) American Regent, Inc., a New York corporation, wholly owned by Luitpold Pharmaceuticals, Inc. (hereafter collectively referred to as “Respondent Daiichi”) (collectively referred to as “Respondents”); Respondents having been furnished thereafter with a copy of a draft 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

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed 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 makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent 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

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of Germany, with its office 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. Within FMCNA there are three main operating units: (1) Fresenius Medical Services, which provides dialysis services; (2) Renal Therapies Group, which manufactures, sells and distributes equipment, supplies and pharmaceuticals used primarily in the treatment of hemodialysis, and (3) Renal Research Institute, which engages in dialysis research and development.

2. Respondent 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.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

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ORDER**I.**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Fresenius” means Fresenius Medical Care AG & Co. KGaA, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries (including Fresenius Medical Care Holdings, Inc.), divisions, groups, and affiliates controlled by Fresenius Medical Care AG & Co. KGaA, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Daiichi” means Daiichi Sankyo Company, Ltd., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries (including Daiichi Sankyo, Inc., Luitpold Pharmaceuticals, Inc., and American Regent, Inc.), divisions, groups and affiliates controlled by Daiichi Sankyo Company, Ltd., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Luitpold” means Luitpold Pharmaceuticals, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries (including American Regent, Inc.), divisions, groups and affiliates controlled by Luitpold Pharmaceuticals, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- D. “Commission” means the Federal Trade Commission.

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- E. “ANDA” means Abbreviated New Drug Application filed with the United States Food and Drug Administration pursuant to 21 C.F.R. Part 314.
- F. “Clinic” means a facility that provides hemodialysis or peritoneal dialysis services to patients suffering from end stage renal disease. For purposes of this Order, “Clinic” does not include in-hospital-based dialysis units for acute kidney events or hospital-based clinics managed by Respondent Fresenius.
- G. “CMS” means the Centers for Medicare & Medicaid Services.
- H. “Fresenius Clinic” means a Clinic that is wholly owned, managed, or controlled by Respondent Fresenius or is a joint venture between Respondent Fresenius and another Person.
- I. “HHS” means the United States Department of Health & Human Services including all of its agencies and offices including, but not limited to, CMS.
- J. “HHS-CMS Requirement” means:
 - 1. any statute or regulation, including, but not limited to, 42 U.S.C. § 1395w-3a, and 42 C.F.R. Part 414, Subparts J and K;
 - 2. any HHS review or study of Manufacturer’s Average Sales Price and other prices, comparisons of such prices, or modifications of payment amounts for drug products, including, but not limited to 42 U.S.C. § 1395w-3a(d); and
 - 3. any HHS or CMS guidance, ruling, statement of policy, or agreement Relating To or affecting the

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average sales price payment methodology as set forth in 42 U.S.C. § 1395w-3a, including, but not limited to the valuation of intra-company transfer prices for the purposes of calculating, or determining payment of, the Manufacturer's Average Sales Price for Venofer.

- K. "License Agreement" means the "License, Distribution, Manufacturing and Supply Agreement by and between Luitpold Pharmaceuticals, Inc., American Regent, Inc. and Fresenius USA Manufacturing, Inc. July 8, 2008," attached as Confidential Exhibit A to this Order. For purposes of this Order, the License Agreement includes sales and distribution contracts between Respondent Daiichi and its Venofer customers that have or will be assumed and serviced by Respondent Fresenius.
- L. "Manufacturer's Average Sales Price" has the same meaning as that in 42 U.S.C. § 1395w-3a(c), including any supplements, modifications, amendments, or changes, thereto, and any HHS or CMS guidance, ruling, statement of policy, or agreement relating thereto.
- M. "Material Confidential Information" means competitively sensitive, proprietary, and all other information that is not in the public domain owned by or pertaining to a Person or a Person's business, and includes, but is not limited to, all customer lists, price lists, contracts, cost information, marketing methods, patents, technologies, processes, or other trade secrets.
- N. "Person" means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, division, or department, including HHS and CMS, or other business or legal entity.

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- O. “Relating To” means pertaining in any way to, and is not limited to that which pertains exclusively to or primarily to.
- P. “Venofer” means a drug product covered by NDA 21-135, in all dosage forms, formulations, line extensions and package configurations and comprising iron sucrose as an active ingredient, used for the treatment of anemia in end stage renal disease kidney dialysis patients, and any improvements to such formulations or dosages as hereafter may be developed and marketed, and including any next generation parenteral iron product, including VIT-45 (ferric carboxymaltose) that may be developed and marketed in the United States.

II.**IT IS FURTHER ORDERED** that:

A. Respondent Fresenius shall:

- 1. For purposes of reporting the Manufacturer’s Average Sales Price for Venofer to CMS as required under the provisions of 42 U.S.C. § 1395w-3a, include the value of all intra-company transfers of Venofer to Fresenius Clinics; and
- 2. For purposes of calculating the Manufacturer’s Average Sales Price for Venofer, report the price of each such intra-company transfer described in Paragraph II.A.1. at no greater than the lesser of:
 - a. the lowest per unit (as established by the Secretary of HHS under 42 U.S.C. § 1395w-3a(b)(2)(B)) price of Venofer sold by Luitpold to a purchaser (excluding sales exempted in 42 U.S.C. § 1395w-

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3a(c)(2)) in the United States, attached as Confidential Exhibit B, as of the date the Agreement Containing Consent Order was signed by Respondent Fresenius, or

- b. the lowest per unit (as established by the Secretary of HHS under 42 U.S.C. § 1395w-3a(b)(2)(B)) price of Venofer sold by Respondent Fresenius to any purchaser (excluding sales exempted in 42 U.S.C. § 1395w-3a(c)(2)) in the United States. *Provided, however*, Respondent Fresenius:

- (1) shall not be required to comply with this Paragraph II.A.2.b. unless and until the date that the United States Food and Drug Administration has issued its final approval of a generic Venofer ANDA; and

- (2) the provisions of this Paragraph II.A.2.b. shall expire on December 31, 2011, after which date Respondent Fresenius shall comply with Paragraph II.A.2.a.

- 3. If any change or modification to an HHS-CMS Requirement is implemented that changes or modifies Respondent Fresenius' obligations pursuant to Paragraph II.A. of this Order ("Change"), such that Paragraph II.A. conflicts or interferes with Respondent Fresenius' ability to comply with, or CMS's ability to enforce, such Change, then the Change shall terminate Respondent Fresenius' obligations pursuant to Paragraph II.A. of this Order. *Provided, however*, CMS, in its sole authority, shall determine whether Paragraph II.A. conflicts or interferes with Respondent Fresenius' ability to comply with, or CMS's ability to enforce, such Change. *Provided, further, however*, that before Respondent Fresenius' obligations under

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Paragraph II.A. terminate, Respondent Fresenius (1) shall receive a statement from CMS notifying Respondent Fresenius that the Change now regulates Respondent Fresenius' calculation of the value of intra-company transfers of Venofer to Fresenius Clinics for purposes of reporting the Manufacturer's Average Sales Price for Venofer to CMS, and (2) shall have complied with the reporting requirements of Paragraph VII.

- B. Respondent Fresenius shall not, directly or indirectly, discuss with, or provide, disclose or otherwise make available to, Respondent Daiichi, or any person working on behalf of Respondent Daiichi, any Material Confidential Information Relating To Respondent Fresenius' pricing of Venofer or Respondent Fresenius' costs of manufacture, sale, or distribution of Venofer, unless specifically provided for in the License Agreement.
- C. The purpose of Paragraph II of this Order is to ensure the continuation of the supply and competitive pricing of Venofer in the same manner as existed at the time of the announcement of the License Agreement, and to remedy the lessening of competition alleged in the Commission's Complaint.

III.

IT IS FURTHER ORDERED that Respondent Daiichi shall not, directly or indirectly, discuss with, or provide, disclose or otherwise make available to, Respondent Fresenius, or any Person working on behalf of Respondent Fresenius, any Material Confidential Information Relating To Respondent Daiichi's pricing of Venofer or Respondent Daiichi's costs of manufacture, sale, or distribution of Venofer, unless specifically provided for in the License Agreement.

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IV.**IT IS FURTHER ORDERED** that:

- A. Nothing in this Order shall prevent Respondent Fresenius from complying with any HHS-CMS Requirement; and
- B. Nothing in this Order shall release Respondent Fresenius from any potential civil or administrative claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-33; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the exclusion statute, 42 U.S.C. § 1320a-7(b)(7); or any common law theories of fraud, unjust enrichment, payment by mistake, breach of contract, or disgorgement, in connection with its calculation and reporting of the Manufacturer's Average Sales Price.

V.

IT IS FURTHER ORDERED that, for the term of this Order, Respondents shall not, without providing advance written notification to the Commission in the manner described in this paragraph, directly or indirectly modify, change or amend the License Agreement. Said advance written notification shall contain (i) a detailed description of the proposed modification, change, or amendment to such agreements, and (ii) documents discussing the reasons for the proposed modification, change, or amendment (hereinafter referred to as "the Notification"), *provided, however*, (i) no filing fee will be required for the Notification, (ii) an original and one copy of the Notification shall be filed only with the Secretary of the Commission and need not be submitted to the United States Department of Justice. Respondents shall provide the Notification to the Commission at least thirty (30) days prior to instituting the modifications, changes, or amendments (hereinafter referred to as the "first

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waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents shall not institute changes to the agreements until thirty (30) days after submitting such additional information or documentary material. Early termination of the waiting periods in this paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition.

VI.**IT IS FURTHER ORDERED** that:

- A. The Commission may, at any time after the Order becomes final, appoint a Monitor to assure that Respondent Fresenius expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order.
- B. Not later than ten (10) days after appointment of a Monitor, Respondent Fresenius shall execute an agreement 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 Respondent Fresenius' compliance with the terms of this Order in a manner consistent with the purposes of this Order.
- C. No later than one (1) day after the Monitor is appointed pursuant to this Paragraph, Respondent Fresenius shall, pursuant to the Monitor Agreement and to this Order, transfer to the Monitor all the rights, powers, and authorities necessary to permit the Monitor to perform his or her duties and responsibilities in a manner consistent with the purposes of this Order.

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- D. In the event a substitute Monitor is required, the Commission shall select the Monitor, subject to the consent of Respondent Fresenius, which consent shall not be unreasonably withheld. If Respondent Fresenius has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent Fresenius of the identity of any proposed Monitor, Respondent Fresenius shall be deemed to have consented to the selection of the proposed Monitor. Respondent Fresenius shall comply with the terms of Paragraph VI.B. and VI.C. after the appointment of the substitute Monitor.
- E. Respondent Fresenius 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 Respondent Fresenius' compliance with the terms of this Order, 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 this Order and in consultation with the Commission, including, but not limited to:
 - a. Assuring that Respondent Fresenius expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order; and
 - b. Assuring that Material Confidential Information is not received or used by Respondent Fresenius, except as allowed in this Order.
 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.

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3. The Monitor shall serve for such time as is necessary to monitor Respondent Fresenius' compliance with the provisions of this Order.
4. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent Fresenius' 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 Respondent Fresenius' compliance with its obligations under this Order. Respondent Fresenius shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent Fresenius' compliance with this Order.
5. The Monitor shall serve, without bond or other security, at the expense of Respondent Fresenius on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent Fresenius, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission.
6. Respondent Fresenius shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with

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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 Monitor.

7. Respondent Fresenius shall report to the Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondent Fresenius, with respect to the performance of Respondent Fresenius' obligations under this Order.
 8. Within one (1) month from the date the Monitor is appointed pursuant to this paragraph, every sixty (60) days thereafter, and otherwise as requested by the Commission, the Monitor shall report in writing to the Commission concerning performance by Respondent Fresenius of its obligations under this Order.
 9. Respondent Fresenius may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Monitor from providing any information to the Commission.
- F. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement Relating To Commission materials and information received in connection with the performance of the Monitor's duties.

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- G. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph VI.
- H. 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 this Order.

VII.**IT IS FURTHER ORDERED** that:

- A. Beginning thirty (30) days after the date this Order becomes final, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the terms of this Order.
- B. Within thirty (30) days after Respondent Fresenius terminates its reporting of the Manufacturer's Average Sale Price of Venofer to CMS, Respondent Fresenius shall submit to the Commission a written report detailing the circumstances of such termination. Respondent Fresenius shall include in such report a written statement from CMS documenting the termination of its reporting of the Manufacturer's Average Sale Price for Venofer to CMS.
- C. Within ten (10) days after the United States Food and Drug Administration has approved a generic Venofer ANDA, Respondent Fresenius shall submit to the Commission and CMS a report stating that the ANDA was approved.

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D. Within ten (10) days after Respondent Fresenius sells Venofer to a purchaser at a price pursuant to Paragraph II.A.2.b., Respondent Fresenius shall submit to the Commission and CMS a report stating:

1. the price it is charging for Venofer to a purchaser pursuant to Paragraph II.A.2.b., and
2. when it began selling Venofer at that price.

The reporting requirements of this Paragraph VII.C. shall apply every time Respondent Fresenius changes the price it is selling Venofer to a purchaser pursuant to Paragraph II.A.2.b.

E. If, pursuant to Paragraph II.A.2.b., Respondent Fresenius changes how it reports the price of each intra-company transfer described in Paragraph II.A.1, for purposes of calculating the Manufacturer's Average Sales Price for Venofer, then by January 10, 2012, Respondent Fresenius shall submit to the Commission and CMS a report stating when and if Respondent will revert to the obligations in Paragraph II.A.2.a.

F. Within thirty (30) days after any Change as described in Paragraph II.A. of this Order and before Respondent Fresenius terminates its obligations under Paragraph II.A., Respondent Fresenius shall submit to the Commission a written report detailing the circumstances of such Change and an explanation of why such Change supercedes Respondent Fresenius' obligations pursuant to Paragraph II.A. of this Order. Such report shall include a statement from CMS notifying Respondent Fresenius that the Change now regulates Respondent Fresenius' calculation of the Manufacturer's Average Sales Price for Venofer to CMS.

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- G. Beginning twelve (12) months after the date this Order becomes final, and annually thereafter on the anniversary of the date this Order becomes final, until the Order terminates, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which the Respondent is complying and has complied with this Order. Respondent Fresenius shall submit at the same time a copy of these reports to the Monitor, if any Monitor has been appointed.

VIII.

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

- A. Any proposed dissolution of that Respondent;
- B. Any proposed acquisition, merger, or consolidation of that Respondent; or
- C. Any other change in that 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 Order.

IX.

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 each Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, each Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission to:

Decision and Order

- A. access, during business office hours of 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 such Respondent related to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order shall terminate the earlier of:

- A. Ninety (90) days after CMS ceases to require Respondent Fresenius to report the Manufacturer's Average Sales Price for Venofer to CMS; or
- B. On October 20, 2018.

By the Commission.

CONFIDENTIAL EXHIBIT A
[Redacted From Public Record But Incorporated By
Reference]

Analysis to Aid Public Comment

CONFIDENTIAL EXHIBIT B
[Redacted From Public Record But Incorporated By
Reference]

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

I. Introduction

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Fresenius Medical Care Ag & Co. KGaA (“Fresenius”) and Daiichi Sankyo Company, Ltd. (“Daiichi”), which is designed to remedy the effects that would otherwise result from Fresenius’s proposed acquisition of an exclusive sublicense from Daiichi’s wholly owned subsidiary Luitpold Pharmaceuticals, Inc. (“Luitpold”) to manufacture and supply Venofer in the United States (hereinafter “License Agreement”). Venofer is an intravenously-administered preparation of iron sucrose that is used primarily to treat iron deficiency anemia in patients with chronic kidney disease undergoing dialysis treatment.

Pursuant to a License, Distribution, Manufacturing and Supply Agreement dated July 8, 2008, Luitpold and Vifor (International) Inc. agreed to grant Fresenius 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. Luitpold retains the right to sell Venofer in the United States to any other customer, including hospitals, doctor’s offices, and

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hospital-based dialysis clinics. The transaction is purely vertical since Fresenius does not sell products that compete with Venofer.

The Commission's Complaint alleges that the proposed acquisition, if consummated, would violate 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, by enabling Fresenius to increase prices it charges its own clinics, which, in turn, would raise reimbursement rates that the Centers for Medicare & Medicaid Services ("CMS") pays for Venofer. The proposed Consent Agreement would remedy the alleged violations by limiting Fresenius's ability to inflate the intra-company transfer price it reports to CMS for Venofer as a mechanism to increase reimbursement rates.

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order.

II. The Parties

Fresenius is the world's largest provider of dialysis products and services to patients suffering from chronic kidney disease, a condition that affects 1.6 million people worldwide. Fresenius is already vertically integrated in that it provides dialysis services through its approximately 1,650 owned or managed dialysis clinics and supplies its own and other clinics with a broad range of dialysis-related products, such as hemodialysis machines, dialyzers and related disposable products.

Daiichi, through its wholly owned subsidiary Luitpold, licenses Venofer from Vifor (International) Inc., a Swiss

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pharmaceutical company that developed the product. Luitpold's subsidiary, American Regent, Inc., markets and distributes all of Luitpold's injectable products, including Venofer, to customers in the United States.

III. Intravenous Iron

Intravenous ("IV") iron is critical for the effective treatment of dialysis patients, the vast majority of whom suffer from chronic anemia. Without IV iron treatments, dialysis patients would suffer significantly higher mortality rates and a lower quality of life. In the United States, Luitpold's Venofer and Ferrlecit, which is manufactured by Watson Pharmaceutical Inc. ("Watson"), are the two IV iron products used most commonly to treat iron deficiency anemia in patients undergoing chronic hemodialysis. These second-generation IV iron drugs do not induce the side effects associated with first-generation IV iron products. Because of these side effects, sales of first generation IV irons in the United States are minimal.

The U.S. market for second-generation IV iron is highly concentrated. Luitpold and Watson are the only two suppliers of these drugs in the United States. In addition, entry into this market would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the effects of the proposed transaction.

IV. Reimbursement for Intravenous Iron

Approximately 80 percent of outpatient dialysis services, for patients of all ages, are reimbursed under the Medicare Part B end-stage renal disease ("ESRD") program, at an annual cost of \$7.9 billion, of which \$2.9 billion was for separately billable drugs, with IV iron payments accounting for \$400 million. Medicare reimburses dialysis clinics based on the drug manufacturer's Average Sales Price ("ASP") plus six percent.

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ASP is calculated by averaging the prices paid by all customers, including any discounts or rebates. A clinic's profit depends not just on how much it pays for the product but the difference between the clinic's acquisition price and the average sale price. An independent clinic, one not vertically integrated with the sale of the product, prefers, all other things equal, an acquisition price that maximizes the difference between its acquisition cost and the average selling price.

The reimbursement system will change, beginning as early as 2011 and completely by 2014. On July 15, 2008, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"), which will make substantial changes to the Medicare program relating to dialysis services and, once fully implemented, would eliminate the regulations that give rise to the concerns created by the proposed transaction. MIPPA mandates that CMS start a process of shifting from a system in which it pays separately for physician-administered drugs for dialysis patients to a system in which all the costs of providing care to dialysis patients would be bundled together into a single capitated payment, beginning on January 1, 2011 and phased in until full implementation is achieved on January 1, 2014. Once the change from a separately-billed, ASP-based payment for Venofer to a universal bundled payment for dialysis services is in effect, the adverse effects of the proposed transaction on reimbursement rates will disappear.

IV. Competitive Effects

Unremedied, the proposed transaction would give Fresenius, the largest provider of ESRD dialysis services in the United States, the ability to increase Medicare reimbursement payments for Venofer. After the transaction, the competitive market will no longer determine the price that Fresenius's clinics will pay for IV iron. Instead, the price Fresenius's clinics pay will become an internal transfer price, and that internal transfer price could become the price that Fresenius reports as the price it charges its

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own clinics for the product. Increasing the internal transfer price would, in turn, increase ASP and, hence, reimbursement to clinics, including Fresenius, for their use of Venofer. Unlike a “real” price increase, it would be costless for Fresenius to inflate its internal transfer price to CMS because it would not impact Fresenius’s actual cost of providing Venofer to its patients, nor would it adversely affect demand. In fact, artificially raising ASP would increase the demand for Venofer among other dialysis clinics because it would cause reimbursement levels to go up.

V. The Consent Agreement

The proposed order reduces Fresenius’s ability to report inflated intra-company transfer prices to CMS for Venofer. Under the proposed order, Fresenius would be restricted from reporting an intra-company transfer price higher than the level set forth in the order. That level is derived from current market prices. The order further provides that if a generic Venofer product receives final approval by the United States Food and Drug Administration, Fresenius would be required to report its intra-company transfer price at either (1) the level set forth in the order or (2) the lowest price at which Fresenius sells Venofer to any customer, whichever is lowest, until December 31, 2011. On January 1, 2012, the order removes the lowest-priced-customer restriction, while the level set forth in the order remains in place. By 2012, at least 50 percent of ESRD dialysis services will be covered under the capitated reimbursement system implemented by MIPPA. The order also provides that if CMS implements regulations that eliminate the potential anticompetitive harm of this transaction, those regulations will supersede the order.

The order accomplishes two goals. First, it prevents the acquisition from driving up ASP and reimbursement rates by requiring Fresenius to report its transfer price in line with current market conditions. Second, it is designed to capture potential near-term changes in the market caused by generic entry, should it

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occur, and to ensure that the price Fresenius reports to CMS reflects the competitive impact of such future generic competition. When fully implemented, the reimbursement methodology of the new bundled pricing system will eliminate the concerns raised by the transaction. Therefore, the price-adjustment provision expires as the reimbursement mechanism changes.¹

The order also prohibits Luitpold and Fresenius from sharing confidential business information relating to the manufacture, sale, or distribution of Venofer, as Luitpold will continue to sell Venofer to non-dialysis clinics, and requires the parties to provide notice to the Commission prior to modifying the License Agreement. Finally, to enable the Commission to ensure compliance with the order, the proposed order provides that the Commission may appoint a Monitor Trustee. The Commission has not determined to appoint a monitor at this time, however, because currently it does not appear that compliance with the order would be time consuming or require particular expertise. Nevertheless, should it become necessary or appropriate, the proposed order requires Fresenius and Daiichi to execute an agreement conferring upon the Interim Monitor all of the rights and powers necessary to permit the monitor to satisfy his responsibilities.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

¹ The Commission is grateful to CMS staff for assisting the Commission as it considered the competitive implications of the proposed transaction and crafted an appropriate remedy.

Complaint

IN THE MATTER OF

**BIOQUE TECHNOLOGIES, INC.,
VITTORIO A. BONOMO,
AND
CHRISTINE A. GUILMAN**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4237; File No. 082 3095**Complaint, October 22, 2008 – Decision, October 22, 2008*

This consent order addresses advertising for Serum GV, represented by the respondents to be an effective treatment for skin cancer. The order requires the respondents to have competent and reliable scientific evidence substantiating any claims that a covered product or service is an effective treatment for skin cancer, including melanoma; prevents melanoma; is recognized by the medical profession as an effective treatment for skin cancer; or is clinically proven to prevent or treat melanoma. The order further requires that such claims be true and non-misleading. The order requires the respondents to possess competent and reliable scientific evidence for any claims about the absolute or comparative benefits, performance, efficacy, safety, or side effects of any covered product or service. The claims also must be true and non-misleading. The order prohibits the respondents from making misrepresentations about the existence, contents, validity, results, conclusions, or interpretations of any test or study. The order does not prohibit the respondents from making representations for any drug that are permitted by the Food and Drug Administration. The order requires the respondents to send to the consumers identified in the order a notification letter drafted by the FTC to inform them about the consent agreement. The order provides for the payment of \$9,035.85, the full amount of sales of the product, to the Commission. Additional provisions require the respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure (for the corporate respondent) and changes in employment (for the individual respondents) that might affect compliance obligations under the order; and to file compliance reports with the Commission.