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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-

DECISION AND ORDER
[Public Record Version]

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 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 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.

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.

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 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.

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-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 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.

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 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.

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.

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 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.

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.

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.

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:

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. Ten years after the date on which the Order becomes final.

By the Commission.

Donald S. Clark
Secretary

SEAL

ISSUED:

CONFIDENTIAL EXHIBIT A

[Redacted From Public Record Version But Incorporated By Reference]

CONFIDENTIAL EXHIBIT B

[Redacted From Public Record Version But Incorporated By Reference]