

**UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION**

In the Matter of

**FRESENIUS MEDICAL CARE AG & CO.
KGaA,
a German partnership,**

and

**DAIICHI SANKYO COMPANY, LTD.,
a Japanese corporation.**

File No. 081-0146

AGREEMENT CONTAINING CONSENT 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 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 “Proposed Respondents”), and it now appearing that Proposed Respondents are willing to enter into this Agreement Containing Consent Order (“Consent Agreement”) to cease and desist from certain acts and practices and providing for other relief;

IT IS HEREBY AGREED by and between Proposed Respondents, by their duly

authorized officers and attorneys, and counsel for the Commission that:

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. Proposed Respondents admit all the jurisdictional facts set forth in the draft of Complaint here attached.
4. Proposed Respondents waive:
 - a. any further procedural steps;
 - b. the requirement that the Commission’s Decision and Order, attached hereto and made a part hereof, contain a statement of findings of fact and conclusions of law;
 - c. all rights to seek judicial review or otherwise to challenge or contest the validity of the Decision and Order entered pursuant to this Consent Agreement; and
 - d. any claim under the Equal Access to Justice Act.
5. Each Proposed Respondent shall submit an initial report, pursuant to Section 2.33 of the Commission’s Rules, 16 C.F.R. § 2.33, within fifteen (15) days of the date on which it executes this Consent Agreement and every thirty (30) days thereafter until the Decision and Order becomes final. Each such report shall be signed by the Proposed Respondent

and shall set forth in detail the manner in which the Proposed Respondent has to date complied or has prepared to comply, is complying, and will comply with the Decision and Order. Such reports will not become part of the public record unless and until the Consent Agreement and Decision and Order are accepted by the Commission for public comment.

6. This Consent Agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this Consent Agreement is accepted by the Commission, it, together with the draft of Complaint contemplated thereby, will be placed on the public record for a period of thirty (30) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this Consent Agreement and so notify Proposed Respondents, in which event it will take such action as it may consider appropriate, or issue or amend its Complaint (in such form as the circumstances may require) and issue its Decision and Order, in disposition of the proceeding.
7. This Consent Agreement is for settlement purposes only and does not constitute an admission by Proposed Respondents that the law has been violated as alleged in the draft of Complaint here attached, or that the facts as alleged in the draft of Complaint, other than jurisdictional facts, are true.
8. This Consent Agreement contemplates that, if it is accepted by the Commission, the Commission may (a) issue and serve its Complaint corresponding in form and substance with the draft of Complaint here attached, and (b) make information public with respect thereto. If such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission may, without further notice to Proposed Respondents, issue the attached Decision and Order in disposition of the proceeding.
9. When final, the Decision and Order shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The Decision and Order shall become final upon service. Delivery of the Complaint and the Decision and Order to Proposed Respondents by any means provided in Commission Rule 4.4(a), 16 C.F.R. § 4.4(a), shall constitute service. Proposed Respondents waive any right they may have to any other manner of service. Proposed Respondents also waive any right they may otherwise have to service of any Appendices incorporated by reference into the Decision and Order, and agree that they are bound to comply with and will comply with the Decision and Order to the same extent as if they had been served with copies of the Appendices, where Proposed Respondents are already in possession of copies of such Appendices.
10. The Complaint may be used in construing the terms of the Decision and Order, and no agreement, understanding, representation, or interpretation not contained in the Decision and Order, or the Consent Agreement may be used to vary or contradict the terms of the Decision and Order.

11. By signing this Consent Agreement, each Proposed Respondent represents and warrants that it can accomplish the full relief contemplated by the attached Decision and Order related to each such Proposed Respondent and that all parents, subsidiaries, affiliates, and successors necessary to effectuate the full relief contemplated by this Consent Agreement are parties to this Consent Agreement.

Signed this _____ day of _____, 2008.

**FRESENIUS MEDICAL CARE AG &
CO. KGaA**

By:

Dr. Ben Lipps
Chief Executive Officer and
Chairman of the Management Board

Dr. Rainer Runte
General Counsel and Chief
Compliance Officer
Member of Management Board

Katherine I. Funk
Sonnenschein Nath & Rosenthal LLP
Counsel for Fresenius Medical Care
Ag & Co. KGaA

DAIICHI SANKYO COMPANY, LTD.

By:

Takashi Shoda
President and Chief Executive Officer
and Representative Director

Wendy C. Goldstein
Patricia M. Wagner
Epstein Becker & Green, P.C.
Counsel for Daiichi Sankyo
Company, Ltd.

FEDERAL TRADE COMMISSION

By:

Elizabeth A. Jex
Attorney
Bureau of Competition

Approved:

Michael R. Moiseyev
Assistant Director
Bureau of Competition

David P. Wales, Jr.
Acting Director
Bureau of Competition