

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Joseph J. Simons, Chairman
Noah Joshua Phillips
Rohit Chopra
Rebecca Kelly Slaughter
Christine S. Wilson

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| In the Matter of | |) |
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| FRESENIUS MEDICAL CARE AG & CO. KGaA, | |) |
| a partnership limited by shares; | |) |
| | |) |
| and | |) |
| | |) |
| NXSTAGE MEDICAL, INC., | |) |
| a corporation. | |) |
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DOCKET NO. C-4671

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Fresenius Medical Care AG & Co. KGaA, (“Fresenius”), a company subject to the jurisdiction of the Commission, has entered into an agreement to acquire Respondent NxStage Medical, Inc. (“NxStage”), a company subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45; that such acquisition, if consummated, would violate 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; and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

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 offices and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany. Fresenius is the parent of Fresenius Medical Care Holdings, Inc., a New York corporation, d/b/a Fresenius Medical Care North America with its offices and principal place of business located

at 920 Winter St., Waltham, MA 02451-1457. Fresenius is engaged in the development, manufacture, sale, and distribution of dialysis equipment and consumables for hemodialysis machines. Further, Fresenius is the largest operator in outpatient hemodialysis clinics in the United States.

2. Respondent Fresenius is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 5 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.
3. Respondent NxStage is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its headquarters located at 350 Merrimack St., Lawrence, Massachusetts, 01843-1748. NxStage is engaged in the development, manufacture, sale and distribution of hemodialysis equipment and consumables for acute and outpatient hemodialysis.
4. Respondent NxStage is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

5. Under the terms of an Agreement and Plan of Merger dated August 7, 2017 (“Agreement”), Fresenius, through its wholly-owned subsidiaries Fresenius Medical Care Holdings, Inc. (“FMCH”) and Broadway Renal Services, Inc. (“Broadway”), will acquire all of the outstanding voting securities of NxStage in a transaction valued at approximately \$2.0 billion (the “Acquisition”). Under the Agreement, Broadway will merge into NxStage with NxStage surviving as a wholly-owned subsidiary of FMCH.

III. THE RELEVANT MARKET

6. For the purpose of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is no broader than the development, manufacture, marketing, distribution, and sale of bloodline tubing sets compatible with hemodialysis machines indicated for chronic renal failure treated in dialysis clinics.
7. A Bloodline tubing set is a single use plastic tube set used during extracorporeal procedures to connect blood access devices to hemodialysis machines. Manufacturers configure bloodline tubing to fit connection points on the hemodialysis machine. Hemodialysis machines have either “open” or “closed” architecture. An open architecture hemodialysis machine has universal connections that are compatible with multiple bloodline brands, whereas a closed architecture

hemodialysis machine requires proprietary bloodlines specifically manufactured for its connection points.

8. For the purpose of this Complaint, the United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in the relevant line of commerce.

IV. THE STRUCTURE OF THE MARKET

9. The U.S. market for bloodline tubing sets indicated for hemodialysis treatment is highly concentrated. Fresenius and NxStage are two of only three current suppliers of bloodline tubing sets for open architecture hemodialysis machines used in clinics with market shares of 59% and 23%, respectively. Nipro Medical Corporation (“Nipro”) is the third supplier with 16% market share. The remaining 2% market share consists of smaller participants supplying proprietary bloodlines for closed architecture hemodialysis machines. NxStage supplies an airless bloodline tubing set, which uses a pressure-oscillating diaphragm that eliminates contact between the patient’s blood and the air that is required to measure pressure. Similarly, Fresenius recently received FDA approval to market its own airless bloodline tubing sets. Fresenius, along with Nipro, offers conventional bloodline tubing sets, which typically use a drip chamber requiring an air gap for measuring pressure.

V. ENTRY CONDITIONS

10. Entry or expansion into the relevant market would not be likely or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the product development, FDA approval, and market adoption times are lengthy. No other entry is likely to occur to deter or counteract the competitive harm likely to result from the Acquisition.

VI. EFFECTS OF THE ACQUISITION

11. The effects of the Acquisition, if consummated, may be to substantially lessen competition 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, in the following ways, among others:
 - i. by eliminating actual, direct, and substantial competition between Fresenius and NxStage in the market for the provision of bloodline tubing sets for hemodialysis machines;
 - ii. by increasing the ability of the merged entity to unilaterally raise prices for bloodline tubing sets for hemodialysis machines; and

- iii. by reducing incentives to improve quality and innovation of bloodline tubing sets for hemodialysis machines.

VII. VIOLATIONS CHARGED

- 12. The Agreement and Plan of Merger described in Paragraph 5 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.
- 13. The Acquisition described in Paragraph 5, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this nineteenth day of February 2019, issues its Complaint against said Respondents.

By the Commission, Commissioners Chopra and Slaughter dissenting.

April J. Tabor
Acting Secretary

SEAL: