ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Becton, Dickinson and Company and C. R. Bard
File No. 171 0140, Docket No. C-4637

I. INTRODUCTION

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Becton, Dickinson and Company ("BD") and C. R. Bard, Inc. ("Bard") (collectively, the "Respondents") that is designed to remedy the anticompetitive effects that would likely result from BD's proposed acquisition of Bard. The proposed Decision and Order ("Order") requires the Respondents to divest all rights and assets related to Bard's tunneled home drainage catheter business and BD's soft tissue core needle biopsy device business to Merit Medical Systems, Inc. ("Merit"). The Order To Maintain Assets requires Respondents to maintain the viability and competitiveness of the businesses pending divestiture.

Pursuant to an Agreement and Plan of Merger, dated as of April 23, 2017, BD and Lambda Corp., a wholly-owned subsidiary of BD, will acquire the issued and outstanding shares of Bard by means of a merger in exchange for cash and stock valued at approximately $24 billion (the "Acquisition"). 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 substantially lessening competition in the U.S. markets for tunneled home drainage catheter systems and soft tissue core needle biopsy devices. The Consent Agreement is designed to remedy the alleged violations by preserving the competition that otherwise would be lost in these markets as a result of the proposed Acquisition.

The Commission has placed the Consent Agreement on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Consent Agreement, along with any comments received, and decide whether it should withdraw from the Consent Agreement, modify the Consent Agreement or Order, or make the Order final.

II. THE RESPONDENTS

BD, headquartered in Franklin Lakes, New Jersey, is a medical technology company that manufactures and sells a broad range of medical supplies, devices, laboratory equipment, and diagnostic products throughout the world. Its operations consist of two business segments: BD Medical and BD Life Sciences. BD Medical provides a broad array of medical technologies and devices to hospitals, clinics, physicians' office practices, pharmacies, pharmaceutical companies, and healthcare workers.

Bard, headquartered in Murray Hill, New Jersey, is a medical technology company that manufactures medical, surgical, diagnostic, and patient care devices sold to hospitals, healthcare

professionals, extended care facilities, and other medical facilities throughout the world. Its operations consist of four principal divisions: Bard Access Systems, Inc., Bard Medical Division, Bard Peripheral Vascular, Inc., and Bard Biopsy Systems.

III. THE RELEVANT MARKETS AND STRUCTURE OF THE MARKETS

A. Tunneled Home Drainage Catheter Systems

Tunneled home drainage catheter systems are medical devices used to treat recurrent fluid buildup in the lungs and abdomen, conditions known as pleural effusions and malignant ascites, respectively. Patients suffering from these conditions, often due to cancer or other serious illnesses, commonly require frequent fluid drainage. Tunneled home drainage catheter systems drain fluid from the lungs (pleural drainage) or abdomen (peritoneal drainage) through a tunneled, indwelling catheter connected to a disposable receptacle. After a medical doctor places the indwelling catheter, the device allows fluid drainage to take place conveniently in a patient's home or in a hospice setting where the patient or a caregiver can attach, remove, replace, and dispose of the drainage receptacle as frequently as needed. Although patients requiring pleural or peritoneal drainage can undergo an outpatient medical procedure when fluid build-up becomes severe, such procedures are not suitable alternatives to tunneled home drainage catheter systems, because they require a patient to make repeated trips to a healthcare facility to see a doctor. Customers likely would not substitute outpatient medical procedures in response to a small but significant increase in the price of tunneled home drainage catheter systems.

BD and Bard are the two largest manufacturers of tunneled home drainage catheter systems in the United States, with a combined market share of approximately 98%. The remaining market share is divided between Rocket Medical plc ("Rocket Medical") and B. Braun Medical Inc. ("B. Braun"). Rocket Medical is a new entrant to the U.S. market, and both Rocket Medical and B. Braun, in addition to having a much smaller share of the market than BD and Bard, have far less recognition among U.S. customers.

B. Soft Tissue Core Needle Biopsy Devices

Soft tissue core needle biopsy devices are used by medical clinicians, typically interventional radiologists or oncologists, to remove small samples of tissue from soft tissue organs for examination and diagnosis. There are no practical alternatives to soft tissue core needle biopsy devices for clinicians seeking to perform a soft tissue biopsy. Other biopsy devices, such as bone or bone marrow biopsy devices, are not approved or intended to be used for soft tissue biopsies. Soft tissue core needle biopsy devices do not include, and are distinguished from, vacuum-assisted biopsy ("VAB") devices which employ a vacuum to remove larger tissue samples. VAB devices are used for breast biopsies involving lesions that are difficult to locate and are not used to perform biopsies of other soft tissues and organs. VAB devices are more complex devices that are sold at a significantly higher price than soft tissue core needle biopsy devices. Accordingly, customers likely would not switch to VAB devices in response to a small but significant increase in the price of soft tissue core needle biopsy devices.

Bard and BD are the two largest manufacturers of soft tissue core needle biopsy devices in the United States, with a combined market share of 60% or greater. Other participants in the market include Cook Medical, Argon Medical Devices, Inc., and Hologic, Inc., but each of these manufacturers has a smaller market share than either Bard or BD. In addition, there is a fringe of other manufacturers with very small market shares.

C. The Relevant Geographic Market

The relevant geographic market for both tunneled home drainage catheter systems and soft tissue core needle biopsy devices is the United States. These relevant products are medical devices regulated by the U.S. Food and Drug Administration ("FDA"). Medical devices sold outside of the United States, but not approved for sale in the United States, are not viable competitive alternatives for U.S. consumers.

IV. COMPETITIVE EFFECTS OF THE TRANSACTION

The proposed Acquisition would likely substantially lessen competition in the U.S. markets for tunneled home drainage catheter systems and soft tissue core needle biopsy devices. The Acquisition would combine the largest and second-largest suppliers of both products in the United States and would substantially increase concentration in already highly concentrated markets. Under the *Horizontal Merger Guidelines*, the Acquisition would presumptively create or enhance market power. By eliminating direct and substantial competition between Respondents, the proposed Acquisition likely would allow the combined firm to exercise market power unilaterally, resulting in higher prices and/or reduced innovation.

V. ENTRY

Entry in the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. New entry into the markets for each of these devices is difficult, time-consuming, and expensive, requiring a significant investment of time and money for product research and development, regulatory approval by the FDA, and the establishment of a sales and marketing infrastructure sufficient to develop customer awareness and acceptance of the products.

VI. THE PROPOSED CONSENT AGREEMENT

The Consent Agreement remedies the competitive concerns raised by the proposed Acquisition by requiring the Respondents to divest all of the assets, facilities, and resources relating to Bard's tunneled home drainage catheter systems business and BD's soft tissue core needle biopsy devices business to Merit. The provisions of the Consent Agreement will enable Merit to become an independent, viable, and effective competitor in the respective relevant markets and maintain the competition that currently exists.

Merit, headquartered in South Jordan, Utah, is a global company with 30 years of experience in the development, manufacture, and distribution of medical devices used in interventional, diagnostic, and therapeutic procedures. Merit offers a portfolio of products that is

highly complementary to the tunneled home drainage catheter systems being acquired. Merit also recently introduced its first soft tissue core needle biopsy device product. Merit possesses substantial industry expertise in these product areas and sells its products to similar customers as BD and Bard. For these reasons, Merit is well positioned to restore the benefits of competition that would be lost due to the Acquisition.

Pursuant to the Order, Merit will receive all rights and assets related to Bard's tunneled home drainage catheter system business and BD's soft tissue core needle biopsy device business, including all of the confidential business information used in those businesses. Merit will own or receive a license to all intellectual property necessary to run the businesses. It will also acquire the equipment used in the manufacturing of the products and all documentation and other information related to the products. Respondents will also contract manufacture products for Merit until it is able to manufacture them itself, and Respondents will provide transitional services to Merit to assist the company in establishing manufacturing capabilities for the divested products.

The Respondents must accomplish the divestitures no later than 10 days after the consummation of the proposed Acquisition. If the Commission determines that Merit is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the Respondents to unwind the sale of assets to Merit and then divest the assets to a Commission-approved acquirer(s) within 180 days of the date the Order becomes final. Pursuant to the Order To Maintain Assets, Respondents must maintain the businesses pending divestiture.

The Commission has agreed to appoint a Monitor to ensure that the Respondents comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of assets to Merit. The Commission has appointed Mazars LLP as the Monitor in this matter. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

VII. OPPORTUNITY FOR PUBLIC COMMENT

The purpose of this analysis is to facilitate public comment on the Consent Agreement to aid the Commission in determining whether it should make the Order final. This analysis is not intended to constitute an official interpretation of the proposed Consent Agreement and does not modify its terms in any way.