



[BILLING CODE: 6750-01S]

FEDERAL TRADE COMMISSION

[File No. 161 0126]

Abbott Laboratories and St. Jude Medical, Inc.; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders -- embodied in the consent agreement -- that would settle these allegations.

DATES: Comments must be received on or before January 26, 2017.

ADDRESSES: Interested parties may file a comment at

<https://ftcpublic.commentworks.com/ftc/abbottjudeconsent> online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write “In the Matter of St. Jude Medical, Inc. /Abbott Laboratories, File No. 161 0126- Consent Agreement” on your comment and file your comment online at

<https://ftcpublic.commentworks.com/ftc/abbottjudeconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write “In the Matter of St. Jude Medical, Inc. /Abbott Laboratories, File No. 161 0126- Consent Agreement” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade

Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Jordan Andrew (202-326-3678), Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for December 27, 2016), on the World Wide Web, at <http://www.ftc.gov/os/actions.shtm>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 26, 2017. Write “In the Matter of St. Jude Medical, Inc. /Abbott Laboratories, File No. 161 0126- Consent Agreement” on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals’ home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone’s Social

Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 CFR § 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR § 4.9(c).¹ Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/abbottjudeconsent> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#!home>, you also may file a comment through that website.

¹ In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR § 4.9(c).

If you file your comment on paper, write “In the Matter of St. Jude Medical, Inc. /Abbott Laboratories, File No. 161 0126- Consent Agreement” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 26, 2017. You can find more information, including routine uses permitted by the Privacy Act, in the Commission’s privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

Analysis of Agreement Containing Consent Orders to Aid Public Comment

INTRODUCTION

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Abbott Laboratories (“Abbott”) and St. Jude Medical, Inc. (“St. Jude”) that is designed to remedy the anticompetitive effects that otherwise would have resulted from Abbott’s proposed acquisition of St. Jude. Under the terms of the proposed Consent Agreement, the parties are required to divest St. Jude’s vascular closure device business and Abbott’s steerable sheath business to Terumo Corporation

(“Terumo”). Abbott is also required to provide notice if it intends to acquire the assets of Advanced Cardiac Therapeutics, Inc. (“ACT”).

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

Pursuant to an Agreement and Plan of Merger dated April 27, 2016, Abbott proposes to acquire St. Jude in exchange for cash and stock valued at approximately \$25 billion (the “Proposed 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 lessening competition in the U.S. markets for vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition.

THE PARTIES

Headquartered in Abbott Park, Illinois, Abbott is a global health care company that offers a large portfolio of vascular products, including coronary, endovascular, vascular closure, electrophysiology, and structural heart devices.

St. Jude, headquartered in St. Paul, Minnesota, is a leading manufacturer of vascular products and medical devices. St. Jude’s vascular products include vascular closure devices, pressure measurement guidewires, percutaneous catheter introducers, heart failure monitoring

devices, cardiac mapping and navigation systems, diagnostic catheters, ablation catheters, and introducer sheaths.

THE RELEVANT PRODUCTS AND STRUCTURE OF THE MARKETS

Vascular closure devices are used to close arterial holes resulting from vascular catheterization procedures. Physicians perform these catheterization procedures to diagnose or treat a cardiovascular condition. Typically, physicians access the femoral artery and direct a specialized catheter to the heart or peripheral arteries to deploy a balloon, diagnose an arrhythmia, or insert a stent or other device. The procedures leave a hole in the artery that must be closed quickly after the catheter is removed. Vascular closure devices provide a fast and effective way for physicians to close these holes while minimizing complications and the time patients must spend recovering from the procedure. Abbott and St. Jude are the two largest suppliers of vascular closure devices in the United States, with a combined market share of over 70%. The only other firms that supply vascular closure devices in the U.S. market are Cardinal Health, Inc. and Cardiva Medical, Inc.

Steerable sheaths are used in electrophysiology procedures to treat complex heart arrhythmias, such as atrial fibrillation. Unlike a fixed sheath, the tip of a steerable sheath is deflectable, which provides better maneuverability and stability for an ablation catheter. Steerable sheaths allow physicians to more easily puncture the transseptal wall of the heart and guide the sheath and catheter into the left atrium or ventricle of the heart. St. Jude is, by far, the largest supplier of steerable sheaths in the U.S. market. Abbott recently entered this market through its acquisition of Kalila Medical, Inc. (“Kalila”) in early 2016. Other suppliers in this market, though not recent entrants, have low single-digit market shares.

Lesion-assessing ablation catheters are used during ablation procedures to treat heart arrhythmias. They also provide feedback to physicians regarding the force being applied by the catheter or the temperature of the ablation target. These products are becoming more important, and more frequently used, as physicians treat more cases of complex atrial fibrillation. Currently, only St. Jude and Biosense Webster Inc. (“Biosense”) provide lesion-assessing ablation catheters in the United States. Abbott and ACT entered into a strategic partnership to develop lesion-assessing ablation catheters.

The United States is the relevant geographic market in which to assess the competitive effects of the Proposed Acquisition. Vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters are all medical devices that are regulated by the FDA. Products that are sold outside the United States, but not approved for sale in the United States, are not alternatives for U.S. consumers.

EFFECTS OF THE ACQUISITION

The Proposed Acquisition would cause significant competitive harm in the U.S. markets for vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters. For vascular closure devices, the merger would combine the largest and second-largest suppliers in the United States. The merger would eliminate the substantial price competition that currently exists between these competitors.

In the market for steerable sheaths, St. Jude is currently the largest supplier in the United States and has held a near-monopoly position in this market for over a decade. Abbott entered this market recently and its product is well positioned to compete head-to-head with St. Jude.

The Proposed Acquisition would eliminate the competition that would have occurred between Abbott and St. Jude in this market.

Finally, if Abbott acquires ACT's lesion-assessing ablation catheter assets, it could eliminate potential competition in the U.S. market for lesion-assessing ablation catheters. ACT's lesion-assessing ablation catheter currently in development would compete directly with offerings from St. Jude and Biosense. It would thus be the third competitor in the highly-concentrated U.S. market for lesion-assessing ablation catheters. Abbott's acquisition of the ACT assets would reduce the additional competition that would have resulted from an additional U.S. supplier of lesion-assessing ablation catheters.

ENTRY

Entry into the U.S. markets for vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The development process for each of these devices is difficult, time-consuming, and expensive. It can take tens of millions of dollars of research and development, significant further funding for clinical trials, and an extensive amount of time to even reach the stage of applying to the FDA for approval. The regulatory approval process itself can also be time-consuming as the FDA reviews the volume of material and data a company submits in support of its application.

THE CONSENT AGREEMENT

The Consent Agreement remedies the competitive concerns raised by Abbott's proposed acquisition of St. Jude by requiring that the parties divest to Terumo all of the assets and resources needed for it to become an independent, viable, and effective competitor in the U.S.

markets for vascular closure devices and steerable sheaths. It also requires Abbott to provide notice if it intends to acquire ACT's lesion-assessing ablation catheter assets.

Terumo possesses the industry experience and reputation necessary to replace competition that would be lost in the U.S. markets for vascular closure devices and steerable sheaths. Terumo is headquartered in Tokyo, Japan. It has been active in the U.S. medical device market for over thirty years and has a U.S. subsidiary based in Somerset, New Jersey. Terumo offers a portfolio of products that are highly complementary to the vascular closure and steerable sheath products being acquired but does not sell any competing products. Through its Interventional Systems business unit, Terumo manufactures and sells guidewires, catheters, and sheaths, as well as other vascular access devices. As a result, it currently sells its products to many of the same customers as Abbott and St. Jude. Terumo is thus well positioned to restore the benefits of competition that would be lost through the Proposed Acquisition.

Pursuant to the Order, Terumo will receive all rights and assets related to St. Jude's vascular closure device business and Abbott's steerable sheath business, including all of the intellectual property used in those businesses. In addition, Terumo will take over part of the facility in Caguas, Puerto Rico where St. Jude currently manufactures most of its vascular closure device products. In order to ensure continuity of supply for certain vascular closure devices and components that are not currently manufactured in the Puerto Rico facility, the Order requires that St. Jude supply Terumo with finished vascular closure devices and components for up to two years while Terumo transitions to independent manufacturing.

To ensure that the divestiture is successful, the Order requires the parties to enter into a transitional services agreement with Terumo to assist the company in establishing its manufacturing capabilities. Further, the Order requires that the parties transfer all confidential

business information to Terumo, as well as provide access to employees who possess or are able to identify such information. Terumo also will have the right to interview and offer employment to employees associated with St. Jude's vascular closure device business and Abbott's steerable sheath business.

The parties must accomplish the divestiture no later than forty-five days after the consummation of the Proposed Acquisition. If the Commission determines that Terumo is not an acceptable acquirer, or that the manner of the divestiture is not acceptable, the Order requires the parties to unwind the sale and accomplish the divestiture within 180 days of the date the Order becomes final to another Commission-approved acquirer.

To ensure compliance with the Order, the Commission has agreed to appoint an Interim Monitor to ensure that Abbott and St. Jude comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to Terumo. Further, the Order allows the Commission to appoint a Divestiture Trustee to accomplish the divestiture should the parties fail to comply with their divestiture obligations. Lastly, the Order terminates after ten years.

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.

By direction of the Commission.

April J. Tabor
Acting Secretary.

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