

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS  
TO AID PUBLIC COMMENT**

*In the Matter of Abbott Laboratories and St. Jude Medical, Inc.  
File No. 161 0126, Docket No. C-4600*

**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.