ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER TO AID PUBLIC COMMENT

In the Matter of Wright Medical Group, Inc. and Tornier N.V., File No. 151 0018

INTRODUCTION

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Order ("Consent Agreement") from Wright Medical Group, Inc. ("Wright") and Tornier N.V. ("Tornier") designed to remedy the anticompetitive effects resulting from the proposed merger of Wright and Tornier. Under the terms of the proposed Decision and Order ("Order") contained in the Consent Agreement, the parties are required to divest to Integra Lifesciences Corporation ("Integra") all of Tornier's rights and assets related to the following reconstructive joint markets: (1) total ankle replacements; (2) total silastic big toe joint replacements; and (3) total silastic toe joint replacements for the second through fifth "lesser" toes.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by 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 and the comments received, and decide whether it should withdraw from the Consent Agreement, modify it, or make it final.

Pursuant to an Agreement and Plan of Merger dated October 27, 2014, Wright and Tornier propose to merge in an all-stock transaction valued at approximately $3.3 billion (the "Proposed Merger"). The Commission's Complaint alleges that the Proposed Merger, 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 total ankle replacements and total silastic toe joint replacements. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in these markets as a result of the Proposed Merger.

THE PARTIES

Headquartered in Memphis, Tennessee, Wright is a global orthopedic company that divides its business into three categories: foot and ankle hardware; upper extremity reconstructive devices; and biologics products.

Tornier is a global medical device company based in Amsterdam, the Netherlands, with U.S. operations headquartered in Bloomington, Minnesota. Tornier's U.S. products include those for the upper extremity joints; lower extremity joints; sports medicine; and biologics.

THE RELEVANT PRODUCTS AND STRUCTURE OF THE MARKETS

I. Total Ankle Replacements

Total ankle replacements are used to treat end-stage ankle arthritis, which develops when cartilage on the bones of the ankle joint wears away and causes bone-on-bone grinding down of the joint surface. Patients with end-stage ankle arthritis experience pain and swelling at the ankle along with difficulty walking. Total ankle replacements reduce the pain while maintaining the motion at the ankle joint. They replace damaged bone and cartilage with a metal tibial tray, a metal talar dome, and a polyethylene bearing. In a fixed bearing total ankle replacement, the polyethylene bearing is locked to the tibial component, while in a mobile bearing system it moves independently. Physicians and their patients would not switch to an alternative product or therapy in response to a small but significant increase in the price of total ankle replacements.

Wright, Tornier, and Stryker Corporation ("Stryker") are the only significant suppliers in the U.S. market for total ankle replacements, accounting for 44%, 19%, and 31% of 2014 sales, respectively. Wright and Tornier are each other's closest competitor. These companies both offer fixed bearing technologies and the only options for revision surgeries, i.e., surgeries to redo a prior total ankle replacement procedure. The other leading supplier, Stryker, supplies the only mobile bearing system in the United States, making it a more distant competitor to Wright and Tornier. The only other U.S. supplier of total ankle replacements, Zimmer Holdings, Inc. ("Zimmer") offers a technology that typically is used only in specialized cases. Zimmer maintains a fringe position in the market.

II. Total Silastic Toe Joint Replacements

Total big toe joint replacements treat severe cases of *hallux rigidus*, an arthritic condition in the first metatarsophalangeal ("MTP") joint of the big toe. Pain and inflammation at the first MTP joint restricts movement of the big toe and leads to difficulty walking. Total big toe joint replacements relieve pain and preserve motion in the big toe.

There are two types of total big toe joint replacements: metal and silastic. Total silastic big toe joint replacements are a distinct antitrust market. Surgeons that favor total silastic big toe joint replacements over metal implants do so for the silastic implants' flexibility and longevity. The silastic implants are also significantly less expensive than total metal big toe joint replacements. Physicians and patients do not view total silastic and total metal big toe joint replacements as reasonably interchangeable. A small but significant increase in the price of total silastic big toe joint replacements would not cause physicians or patients to switch to other products or therapies.

The U.S. market for total silastic big toe joint replacements is highly concentrated. Wright and Tornier are the only significant suppliers of the product, accounting for approximately 60% and 38% of the market, respectively. The next closest competitor to Wright and Tornier—Sgarlato Med LLC—accounts for a nominal share of the market.

Although more rare than in the big toes, severe arthritis also occurs in the MTP joints of the lesser toes. Physicians and patients who use total silastic lesser toe joint replacements would not switch to any other product or procedure in response to a small but significant increase in the price of the total silastic toe joint implants. Wright, Tornier, and OsteoMed supply total silastic lesser toe joint replacements in the United States, and Wright and Tornier are each other's closest competitor. The Proposed Merger would result in a combined market share of approximately 76%.

The relevant geographic market for total ankle replacements and total silastic toe joint replacements is the United States. These 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, do not provide viable competitive alternatives for U.S. consumers.

ENTRY CONDITIONS

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 Merger. To enter or effectively expand in any of the relevant markets successfully, a supplier would need to design and manufacture an effective product, obtain FDA approval, and develop clinical history supporting the long-term efficacy of its product. The new entrant or expanding firm would also need to develop and foster product loyalty and establish a nationwide sales network capable of marketing the product and providing on-site service at hospitals nationwide. Establishing a track record for quality, service, and consistency is difficult, expensive, and typically spans several years.

COMPETITIVE EFFECTS OF THE MERGER

The Proposed Merger would likely result in significant competitive harm to consumers in the markets for total ankle replacements and total silastic toe joint replacements. As particularly close substitutes in each relevant market, Wright and Tornier respond directly to competition from each other with improved products, better service, and lower prices. By eliminating this direct and substantial head-to-head competition, the Proposed Merger likely would allow the combined firm to exercise market power unilaterally, resulting in less innovation and higher prices for consumers.

THE CONSENT AGREEMENT

The Consent Agreement eliminates the competitive concerns raised by the Proposed Merger by requiring the parties to divest to Integra all of the rights and assets needed for it to become an independent, viable, and effective competitor in the U.S. markets for total ankle replacements and total silastic toe joint replacements. The divestitures will maintain the competition that currently exists in each of the relevant markets.

Integra is well positioned to restore the competition that otherwise would be lost through the Proposed Merger. Headquartered in Plainsboro, New Jersey, Integra is a global medical

device company that has experience manufacturing, marketing, and distributing orthopedic devices in the United States, and a track record for quality, service, and consistency. Integra's lower extremity product portfolio is also highly complementary to Tornier's total ankle replacements and total silastic toe joint replacements.

The Order requires Tornier to divest all U.S. assets and rights related to the relevant products, including intellectual property, manufacturing technology, and existing inventory. In order to ensure continuity of supply, the Order requires that the parties supply Integra with total ankle replacements for up to three years and total silastic toe joint replacements for up to one year while Integra transitions to independent manufacturing and works to obtain FDA approval.

To ensure that the divestitures are successful, the Order requires the parties to enter into a transitional services agreement with Integra to assist the company in establishing its manufacturing capabilities and securing all necessary FDA approvals. Further, the Order requires that the parties transfer all confidential business information to Integra, as well as provide access to employees who possess or are able to identify such information. Integra also will have the right to interview and offer employment to employees associated with the relevant products.

The parties must accomplish these divestitures and relinquish their rights to Integra no later than ten days after the Proposed Merger is consummated. If the Commission determines that Integra is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to Integra and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The Order also requires the parties to appoint Quantic Regulatory Services, LLC as interim monitor to ensure the parties comply with the obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the assets and rights to Integra.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.