

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER  
TO AID PUBLIC COMMENT**  
*In the Matter of Zimmer Holdings, Inc. and Biomet, Inc., File No. 141-0144*

**INTRODUCTION**

The Federal Trade Commission (“Commission”) has accepted from Zimmer Holdings, Inc. (“Zimmer”), subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”), which is designed to remedy the anticompetitive effects likely to result from Zimmer’s proposed acquisition of Biomet, Inc. (“Biomet”). Under the terms of the proposed Decision and Order (“Order”) contained in the Consent Agreement, Zimmer and Biomet must divest Zimmer’s Unicompartamental High Flex Knee System (“ZUK”) business in the United States to Smith & Nephew, Inc. (“Smith & Nephew”) and divest Biomet’s Discovery Elbow and Cobalt Bone Cement businesses in the United States to DJO Global, Inc. (“DJO”).

The Consent Agreement has been placed 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 and the comments received, and decide whether it should withdraw from the Consent Agreement, modify it, or make it final.

Pursuant to an agreement signed on April 24, 2014, Zimmer plans to acquire Biomet for approximately \$13.35 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 substantially lessening competition in the U.S. markets for: (1) unicondylar knee implants; (2) total elbow implants; and (3) bone cement. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition.

**THE PARTIES**

Zimmer, headquartered in Warsaw, Indiana, is the third-largest musculoskeletal medical device company in the United States and worldwide, specializing in the design, development, manufacture, and marketing of orthopedic reconstructive products. In 2013, Zimmer generated U.S. revenues of \$2.42 billion.

Biomet, also headquartered in Warsaw, Indiana, is the fourth-largest musculoskeletal medical device company in the United States and the fifth-largest globally. In 2013, Biomet generated U.S. revenues of \$1.86 billion.

## **THE RELEVANT PRODUCTS AND MARKET STRUCTURES**

### **Unicondylar Knee Implants**

Unicondylar knee implants are medical devices that replace damaged bone and cartilage in only one of the knee's three condyles. The most common indication for a unicondylar knee implant is osteoarthritic damage in the medial condyle. In comparison to a total knee implant, which replaces all three condyles, a unicondylar knee implant requires less invasive surgery and allows a patient to have a more natural feeling knee upon recovery from surgery.

Unicondylar knee implants vary in a number of ways; however, one of the most important differences among the implants is whether they have a fixed or mobile bearing. In a fixed bearing implant, a plastic piece is fixed permanently to the end of the tibia. In a mobile bearing knee, the plastic piece moves and glides over the tibia as the knee moves. The mobile bearing places less stress on the bearing surface and may extend the longevity of the implant. Despite these differences, fixed bearing and mobile bearing implants are in the same product market because surgeons regularly substitute between them as they achieve comparable functional outcomes for the same indications.

The market for unicondylar knee implants is highly concentrated. Biomet, which markets the Oxford implant, is the market leader, with a share of at least 44%. Biomet's Oxford is the only mobile bearing knee implant currently on the market. Zimmer, the second-leading supplier of unicondylar knee implants, controls at least 23% of the market with its fixed bearing implant, ZUK. Stryker Corporation ("Stryker") offers two unicondylar knee implants with fixed bearings: the Triathlon PKR and MAKOPlasty, a robotic-assisted surgery option. Stryker's market share is approximately 8%. Johnson & Johnson, through its DePuySynthes Companies ("J&J DePuy"), and Smith & Nephew both offer fixed bearing knee implants and are distant fourth and fifth competitors, maintaining approximately 6% and 3% shares of the market, respectively. Additionally, a number of small, fringe competitors each control a small share of the market, but individually and collectively have limited competitive significance. Absent a remedy, the Proposed Acquisition would produce a single firm controlling at least 67% of the unicondylar knee implant market and substantially increase market concentration.

### **Total Elbow Implants**

Total elbow implants are medical devices that replace damaged bone and cartilage in the elbow joint caused by osteoarthritis or a severe elbow fracture. Total elbow implants replace the elbow joint with a metal hinge that affixes to stems implanted into the humerus and the ulna. There are two types of total elbow implants: linked and unlinked. Linked total elbow implants connect the humeral stem to the ulnar stem with a pin and locking device, providing extra stability where the ligaments surrounding the elbow joint are weak. Unlinked total elbow implants do not connect the humeral stem to the ulnar stem mechanically; instead, they use the patient's natural ligaments to secure the implant. Linked and unlinked total elbow implants are viewed as reasonably interchangeable by health care providers because they treat the same indications and are priced similarly.

The market for total elbow implants is highly concentrated today, and the Proposed Acquisition would increase concentration in this market substantially. Zimmer and Biomet are the two largest suppliers of total elbow implants. Apart from the merging parties, Tornier, Inc. (“Tornier”) is the only other significant supplier of total elbow implants. Zimmer offers two products—the Coonrad/Morrey Total Elbow and the Nexel Total Elbow. The Coonrad/Morrey Total Elbow, developed at the Mayo Clinic, is a cemented, linked total elbow implant with twenty-four years of clinical history. In late 2013, Zimmer launched the Nexel Total Elbow, which updated the Coonrad/Morrey Total Elbow with, among other things, a revised linkage system and instrumentation, and an improved bearing surface. Biomet’s Discovery Total Elbow is also a cemented, linked implant supported by over ten years of clinical history. Tornier launched its Latitude EV implant, a cemented total elbow system capable of converting between a linked and unlinked prosthesis, in the United States in 2013.

### **Bone Cement**

Surgeons use bone cement in a wide variety of joint arthroplasties to affix implants to bones, including the vast majority of knee and elbow implants, as well as many hip and shoulder procedures. Bone cement is available in high, medium, and low viscosities and in non-antibiotic and antibiotic formulations. Surgeons select bone cement based on its viscosity, whether it has an antibiotic component, supporting clinical data, and familiarity. Because surgeons generally use the more expensive antibiotic bone cement only for patients with a high risk of infection, it may be appropriate to analyze the Proposed Acquisition in separate relevant markets for antibiotic and non-antibiotic bone cement. Most customers, however, purchase both types of bone cement through a single contract with a single vendor, and the market participants, competitive dynamics, and entry barriers are the same for both antibiotic and non-antibiotic bone cement. Thus, for convenience and efficiency, it is appropriate to analyze the impact of the Proposed Acquisition in a relevant market for all bone cement products.

Four primary suppliers serve the U.S. bone cement market: Stryker, Zimmer, J&J DePuy, and Biomet, which together account for approximately 98% of all bone cement sales in the United States. Stryker’s Simplex is the market leader, with a share of approximately 40% of the market. Zimmer, the second-largest bone cement supplier, has a market share of approximately 30%. Zimmer derives nearly all of its bone cement revenues from the sale of Palacos, which Zimmer distributes under license from Heraeus Holding. J&J DePuy takes approximately 18% of the market with its SmartSet bone cement, while Biomet’s Cobalt has an approximate 10% market share. The Proposed Acquisition would reduce the number of major suppliers of bone cement in the United States from four to three and increase concentration in this market substantially.

### **THE RELEVANT GEOGRAPHIC MARKET**

The United States is the relevant geographic market in which to analyze the effects of the Proposed Acquisition. Medical devices sold outside of the United States are not viable alternatives for U.S. consumers, as they cannot turn to these products even in the event of a price increase for products currently available in the United States. Further, the U.S. Food and Drug Administration (“FDA”) must approve any medical device before it is sold in the United States, a

process that generally takes a significant amount of time. Thus, suppliers of medical devices outside the United States cannot shift their product into the U.S. market quickly enough to be considered current market participants.

## **ENTRY**

Entry or expansion into the markets for unicondylar knee implants, total elbow implants, and bone cement would not be timely, likely, or sufficient to counteract the likely anticompetitive effects of the Proposed Acquisition. To enter or effectively expand in any of these 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 putative expanding firm also would 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 throughout the country. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market.

## **EFFECTS OF THE ACQUISITION**

Zimmer's acquisition of Biomet would likely result in substantial anticompetitive effects in the unicondylar knee implant market by eliminating substantial head-to-head competition between the two most successful implants. Zimmer's ZUK and Biomet's Oxford are particularly close competitors because of their well-documented clinical success records. As close competitors, customers currently leverage the Oxford and ZUK against each other to obtain better pricing. Additionally, Zimmer and Biomet continually improve features of their unicondylar knee implants in order to win business from physicians. Therefore, absent a remedy, the Proposed Acquisition would likely result in unilateral price effects and reduced innovation.

The Proposed Acquisition would also eliminate substantial competition between Zimmer and Biomet in the market for total elbow implants. Market participants indicate that Zimmer and Biomet total elbow implants are each other's next best alternative based upon design similarities and comparable clinical outcomes. As close substitutes, Zimmer and Biomet currently compete directly, including on price and service.

Zimmer's Palacos and Biomet's Cobalt Bone Cement products are particularly close substitutes that currently compete aggressively against each other. Absent a remedy, the Proposed Acquisition would result in the loss of substantial price competition between Zimmer and Biomet for the sales of their products.

## THE CONSENT AGREEMENT

The Consent Agreement eliminates the competitive concerns raised by the Proposed Acquisition by requiring Zimmer and Biomet to divest all U.S. assets and rights related to Zimmer's ZUK unicondylar knee implant to Smith & Nephew and all U.S. assets and rights related to Biomet's Discovery Total Elbow implant and Cobalt Bone Cement to DJO. This divestiture will preserve the competition that currently exists in each of the relevant markets.

Smith & Nephew is a global specialty pharmaceutical company headquartered in London, United Kingdom. Smith & Nephew employs more than 14,000 employees worldwide with approximately 6,225 employees in the United States. In 2014, Smith & Nephew generated worldwide revenues of approximately \$5.8 billion, of which approximately \$1.5 billion came from its orthopedic reconstruction business.

DJO develops, manufactures, and distributes a wide range of medical devices, including orthopedic implants. Headquartered in Vista, California, DJO employs 5,200 people, and had revenues of approximately \$1.2 billion in 2014. DJO's orthopedic implant business had approximately \$100 million in 2014 revenues.

Pursuant to the Order, Smith & Nephew will receive all U.S. assets and rights related to the ZUK unicondylar knee product, including intellectual property, manufacturing technology, and existing inventory. Zimmer is also required to waive any non-compete employment clauses and assist in facilitating employment interviews between key employees and sales representatives from Zimmer distributors who currently sell the ZUK. The Order further requires Zimmer to provide transitional services to Smith & Nephew to assist them in establishing their manufacturing capabilities and securing all necessary FDA approvals.

The Order requires Biomet to divest all U.S. assets and rights necessary to enable DJO to become an independently viable and effective competitor in the total elbow implant and bone cement markets. Biomet is required to divest to DJO all of its U.S. assets and rights to research, develop, manufacture, market, and sell its total elbow implant and bone cement products, including all related intellectual property, manufacturing technology, and existing inventory. Biomet will also divest all U.S. assets and rights to its bone cement accessories, which consist of mixing and delivery systems that allow surgeons to control the bone cement ingredients to ensure a complete and consistent bone cement mixture and to apply cement onto an implant accurately. Hospitals and group purchasing organizations frequently purchase bone cement and bone cement accessories together. Further, the Order facilitates DJO's hiring of the Biomet sales representatives and employees whose responsibilities are related to bone cement and total elbow implants.

The Order requires Zimmer and Biomet to divest their respective U.S. assets and rights to the divested products no later than ten days after the Proposed Acquisition is consummated or on the date the Order becomes final, whichever is earlier. If the Commission determines that Smith & Nephew or DJO is not an acceptable acquirer, or that the manner of the divestiture is not acceptable, the Order requires Zimmer and Biomet to unwind the sale and divest the products

within six months of the date the Order becomes final to another Commission-approved acquirer or acquirers. In that circumstance, the Commission may appoint a trustee to accomplish the divestiture if the parties fail to divest the products.

The Commission has agreed to appoint an interim monitor to ensure that Zimmer and Biomet 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 assets and rights to Smith & Nephew and DJO.

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.