

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS  
TO AID PUBLIC COMMENT  
*In the Matter of Johnson & Johnson, File No. 111 0160***

**I. Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Johnson & Johnson (“J&J”). The purpose of the proposed Consent Agreement is to remedy the anticompetitive effects that would otherwise result from J&J’s acquisition of the volar distal radius plating system assets of Synthes, Inc. (“Synthes”). Under the terms of the proposed Consent Agreement, J&J is required to divest all assets (including intellectual property) related to its “DVR” volar distal radius plating system business to a third party, enabling that third party to make and sell the DVR for the treatment of distal radius wrist fractures.

The proposed 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 proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement or make it final.

Pursuant to an Agreement and Plan of Merger dated April 26, 2011, J&J proposes to acquire Synthes in exchange for cash and voting securities in a transaction valued at approximately \$21.3 billion. 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 combining the two largest competitors in the U.S. market for volar distal radius plating systems. The proposed Consent Agreement would remedy the alleged violations by replacing the competition that otherwise would be lost in these markets as a result of the acquisition.

**II. The Parties**

J&J is a comprehensive and broad-based manufacturer of products related to all aspects of human health care. In 2011, J&J generated global sales of \$65 billion and U.S. sales of \$28.9 billion. J&J is divided into three business segments: Consumer, Pharmaceutical, and Medical Devices and Diagnostics. The products impacted by the proposed transaction, volar distal radius plating systems, fall within J&J’s Medical Devices and Diagnostics segment.

Synthes is a medical device company that manufactures products in five main product groups: trauma, spine, cranio-maxillofacial, biomaterials, and power tools. In 2011, Synthes generated global sales of \$3.97 billion worldwide and U.S. sales of \$2.14 billion. Synthes’s volar distal radius plating system sales are part of its trauma unit.

### **III. Volar Distal Radius Plating Systems**

Volar distal radius plates are internal fixation devices that are implanted surgically from the underside of the wrist to achieve and maintain proper alignment of the radius bone following a fracture. Distal radius fractures, which are fractures of the portion of the radius bone closest to the wrist, are among the most common fractures in the human body. Distal radius fractures generally occur as a result of an individual bracing for a fall, whether it is a routine slip and fall by an elderly patient with a weak bone structure or a high-energy fall by a young, active patient engaged in sporting activities.

Most patients who experience distal radius fractures do not require surgical intervention and can be treated with simple casting. If the radius bone is displaced, however, it is almost always necessary to realign the fracture surgically. Volar distal radius plating systems are the primary option for treating displaced distal radius fractures in the United States. They are favored by surgeons because they provide solid fracture alignment, are easy to implant, and enable greater patient post-surgical freedom of movement and shorter patient recovery times. Other options exist to treat displaced distal radius fractures, but those alternative methods are typically used only in specialized cases. For the large percentage of displaced distal radius fractures, the clinical benefits of volar distal radius plating systems cannot be matched by the alternative products available on the market, and doctors and their patients would not switch to using products other than volar distal radius plating systems in response to a small but significant increase in the price of these systems.

The U.S. market for volar distal radius plating systems is highly concentrated, with J&J and Synthes controlling over 70 percent of the market as measured by 2010 revenue. The design of the DVR incorporates unique, clinically relevant features that are protected by intellectual property rights. Many surgeons still consider the DVR to be the best volar distal radius plating system on the market, and it accounted for approximately 29 percent of U.S. volar distal radius sales in 2010. Synthes is the leading manufacturer of volar distal radius plating systems in the United States, and accounted for approximately 42 percent of the market by 2010 revenue. Synthes's success selling distal radius plating systems derives in part from its leading position and strong clinical reputation in the overall trauma field. The next closest competitors to J&J and Synthes – Stryker and Acumed – would each be less than one-sixth the size of the combined firm.

The relevant geographic market for volar distal radius plating systems is the United States. Volar distal radius plating systems are medical devices that are regulated by the United States Food and Drug Administration (“FDA”). Volar distal radius plating systems sold outside the United States, but not approved for sale in the United States, are not viable competitive alternatives for U.S. consumers and hence are not in the relevant market.

#### **IV. Competitive Effects and Entry Conditions**

The acquisition would cause significant competitive harm in the market for volar distal radius plating systems. J&J and Synthes are the leading suppliers of volar distal radius plating systems and each other's most significant competitors. J&J and Synthes have responded directly to competition from each other with lower prices and improved products. Although there are a number of other suppliers of volar distal radius plates, they have not gained significant traction among surgeons and have substantially smaller market shares than the merging parties. By eliminating its closest competitor, the acquisition would allow J&J to unilaterally raise prices in the market for volar distal radius plating systems.

Entry would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Both J&J and Synthes employ patented technology in their volar distal radius plating systems. The patents owned by the two companies have prevented competitors from developing products that surgeons consider to be equally effective. Manufacturer product reputation and effective distribution also are important to surgeons and hospitals. Many fringe competitors are limited by their lack of a strong distribution system, and it would take a significant amount of time for one or more current fringe competitors to develop a sufficient reputation for quality, service, and consistency. Therefore, timely and sufficient entry in response to a small but significant price increase is unlikely.

#### **V. The Proposed Consent Agreement**

The proposed Decision and Order resolves the competitive concerns raised by J&J's proposed acquisition of Synthes by requiring the divestiture of J&J's U.S. DVR assets to a qualified buyer no later than ten (10) days after the acquisition is consummated. The parties have selected Biomet, Inc. ("Biomet") as the buyer for the assets to be divested. Although the Commission's competitive concerns are limited to the manufacture and sale of volar distal radius plating systems, the parties elected to divest the entire J&J trauma portfolio, including the volar distal radius plating systems, to Biomet. Biomet is a successful orthopedics company with a recognized brand name, an extensive nationwide sales force, and existing service relationships with surgeons and hospitals, but it currently has no meaningful presence in the volar distal radius plating or trauma product markets. Biomet is thus well positioned to replace the competition that will be eliminated as a result of the proposed transaction. A divestiture of J&J's volar distal radius assets will ensure that Biomet has a recognized high-quality volar distal radius plating system offering, enabling it to compete immediately with the merged entity.

The Commission's merger remedies are intended to maintain or to restore the competitive *status quo*. Based on the evidence gathered in the investigation, the Commission has determined that the divestiture of J&J's volar distal radius plating system assets to Biomet should replicate the competitive conditions for volar distal radius plating systems that existed prior to the proposed transaction between J&J and Synthes.

The proposed Consent Agreement contains a provision that allows the Commission to appoint an interim monitor to oversee J&J's compliance with all of its obligations and performance of its responsibilities pursuant to the Commission's Decision and Order. The interim monitor is required to file periodic reports with the Commission to ensure that the Commission remains informed about the status of the divestitures, about the efforts being made to accomplish the divestitures, and about the provision of services and assistance during the transition period to ensure the success of the DVR divestiture.

Finally, the proposed Consent Agreement contains provisions that allow the Commission to appoint a divestiture trustee if any or all of the above remedies are not accomplished within the time frames required by the Consent Agreement.

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 Decision and Order or to modify its terms in any way.