

***Case No COMP/M.3146 -  
SMITH & NEPHEW /  
CENTERPULSE***

Only the English text is available and authentic.

**REGULATION (EEC) No 4064/89  
MERGER PROCEDURE**

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Article 6(1)(b) NON-OPPOSITION  
Date: 27/05/2003

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Brussels, 27/05/2003

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In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EEC) No 4064/89 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus [...]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE  
ARTICLE 6(1)(b) DECISION

To the notifying parties

Dear Sir/Madam,

**Subject: Case No COMP/M.3146 – Smith & Nephew/Centerpulse  
Notification of 22.04.2003 pursuant to Article 4 of Council Regulation  
No 4064/89<sup>1</sup>**

1. On 22.04.03, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EEC) No 4064/89 by which the undertaking Smith & Nephew plc (“SN” – UK) acquires within the meaning of Article 3(1)(b) of the Council Regulation control of the whole of the undertaking Centerpulse AG (“Centerpulse” – Switzerland) by way of public bid announced on 20.03.03.
2. The Commission has concluded that the notified operation falls within the scope of the Merger Regulation and does not raise serious doubts as to its compatibility with the common market.

#### **I. THE PARTIES AND THE OPERATION**

3. Both companies are active in the industry for medical devices, producing a wide range of orthopaedic devices such as replacement joints, trauma products and a number of other ancillary medical systems to help alleviate pain and promote healing.
4. Furthermore, whilst SN serves the endoscopy and wound management segments, Centerpulse (formerly known as Sulzer Medica AG) develops, manufactures and distributes spinal care products and dental implants.
5. The planned transaction involves the purchase, by SN, of all shares issued and to be issued in Centerpulse, thus constituting an acquisition of sole control over the whole of the latter.

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<sup>1</sup> OJ L 395, 30.12.1989 p. 1; corrigendum OJ L 257 of 21.9.1990, p. 13; Regulation as last amended by Regulation (EC) No 1310/97 (OJ L 180, 9. 7. 1997, p. 1, corrigendum OJ L 40, 13.2.1998, p. 17).

## II. CONCENTRATION

6. The proposed operation is therefore a concentration within the meaning of Article 3(1) of the Merger Regulation.

## III. COMMUNITY DIMENSION

7. The combined aggregate worldwide turnover of the undertakings concerned exceeds EURO 2,500 million (SN EURO [...] and Centerpulse EURO [...] million). The aggregate Community-wide turnover of each party exceeds EURO 100 million (SN EURO [...] million; and Centerpulse EURO [...] million). In each of at least three Member States, namely France, Germany and Italy, each of the parties has a turnover in excess of EURO 25 million, and in each of those Member States the parties' combined aggregate turnover exceeds EURO 100 million. The undertakings concerned do not achieve more than two thirds of their turnover in one and the same Member State. The notified operation has therefore a Community dimension, meeting the thresholds of the Merger Regulation.

## IV. COMPETITIVE ASSESSMENT

### The relevant markets

8. The proposed concentration affects essentially two segments of the orthopaedic industry in which both companies are active, namely hip and knee reconstructive implants.
9. In its previous case *Johnson & Johnson/Depuy*<sup>2</sup>, the Commission held that hip and knee implants constituted separate product markets based on the absence of substitutability from both demand and supply side. In the current case the parties claim that all replacement joints (hip, knee and shoulder implants) should instead belong to the same product market because of the considerable degree of supply side substitution. Their contention is based on the fact that the key stages of the production process for all reconstructive implants are very similar.
10. The results of the market investigation carried out by the Commission with regard to the present transaction do not support the parties' assertions as to the extent of discarding the market definition retained by the Commission in the *Johnson & Johnson/Depuy* case. Despite the fact that all main competitors produce the entire range of implants, a change in the type of replacement joint entails substantial modifications of the manufacturing process. Moreover, the need of clinical evidence supporting implants' reliability is the key to penetrate the market and may constitute a factor capable of delaying a rapid and timing entry by new comers, even in the event they are already active players in neighbouring segments.
11. In the segment of hip implants, the Commission has identified in the past one single product market irrespective of the technical variations as well as surgical philosophies which differentiated such products in terms of characteristics and price (e.g. Charnley versus Muller implants, cemented v. cementless implants, primary v. revision implants). There seemed to be indeed a high degree of both demand and supply side substitutability.

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<sup>2</sup> Case No IV/M. 1286 – Johnson & Johnson /DePuy.

12. The market investigation in the present case has confirmed again the considerations above : in terms of demand, the different designs are regarded by most customers as satisfactory substitutes. Despite particular preferences, the medical staff is typically familiar with the various surgical philosophies and/or is trained to face a change of design in a relatively short time. As to supply substitutability is concerned, the results of the Commission's enquiry reveal that all large implant manufacturers specialised in a particular philosophy can easily switch to a different one without incurring in significant alterations of production processes and major costs.
13. With regard to knee implants, instead, a further distinction was drawn in the *Johnson & Johnson/De Puy* case between fixed-bearing knees and mobile-bearing knees based on the following considerations: from the demand side these products were hardly substitutable because of a number of different characteristics (fixed-bearing implants allowed less mobility to the patient, were easier to implant and lower cost, whereas mobile-bearing implants were more technically advanced, allowed more mobility and were more expensive); from the supply-side the degree of substitutability was very limited. In particular, mobile-bearing implants were protected by patents, which rendered unlikely an easy entry of fixed-bearing implants manufacturers into the mobile-bearing segment. However, in the current case the parties contend that the segmentation between fixed versus mobile knee implants is no more appropriate as the patents protecting the mobile-bearing technology have in the meantime expired.
14. The parties' contentions have been supported by the results of the market investigation, which confirm that patents are not longer an inhibiting factor to enter the mobile bearing segment. All major manufacturers produce both types of knee implants, a broad number of models being available on the market.
15. As to the geographic markets, the parties claim that they are EEA-wide due to a number of factors: the entry into force of the medical devices directive which has harmonised the quality standard; the fact that the main players in the sector tend to centralise their manufacturing in few plants located around the world; low costs of transport; homogeneity of competitive conditions reigning throughout the EEA; greater use by customers of public tenders.
16. Despite an incipient tendency towards a wider (European) scope resulting from the implementation of the EU directive on medical devices and the fact that most main players in the industry offer the same products across Europe, the market investigation in the present case has identified a number of factors militating in favour of national geographic markets, in accordance with the finding with the previous case. Firstly market shares of the major players in this sector vary from country to country, and so do prices. Secondly, and more importantly, in the sector concerned by the transaction both training and assistance from the suppliers are still regarded as essential by hospitals and doctors. Finally, similarly to other medical sectors, the presence of public reimbursement systems in a large number of EU countries has partitioned off the markets at national level.

### **Market structure and competitive conditions<sup>3</sup>**

17. Following the transaction, the new entity will become the European market leader in the overall market of replacement joints, reaching a combined market share in the EEA of

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<sup>3</sup> Market shares are approximate percentages based on the data provided by the notifying party and main competitors in the course of the market investigation.

approximately [20-30]% (Centerpulse is the European market leader in hip implants with [20-30]% and ranks number two in knee joints with [10-20]%, while Smith & Nephew is a small player in hip implants ([0-10]%) and a more significant one in knees joints ([5-15]%). The closest competitors will be Johnson & Johnson/Depuy with an EEA market share of something in the range of [15-25]%, Stryker with about [10-20]% and Zimmer with [5-15]%).

18. At national level, the operation will have a significant impact in a number of countries. More specifically, with respect to hip implants, the new entity will become market leader in Netherlands with a combined market share between [35-45]% (Smith & Nephew [10-20]% plus Centerpulse [20-30]%), Italy [30-40]% (Smith & Nephew [0-10]% plus Centerpulse [25-35] %), Germany [30-40]% (Smith & Nephew [0-10]% plus Centerpulse [25-35]%) Belgium [25-35]% (Smith & Nephew [10-20]% plus Centerpulse [10-20]%), and France [20-30]% (Smith & Nephew [0-10]% plus Centerpulse [15-25]%).
19. As for knee implants, the new entity will become market leader in Belgium with a combined market share of [30-40]% (Smith & Nephew [20-30]% plus Centerpulse [5-15]%), Germany [25-35]% (Smith & Nephew [5-15]% plus Centerpulse [15-25]%), Netherlands [20-30]% (Smith & Nephew [15-25]% plus Centerpulse [0-10]%), Italy [20-30]% (Smith & Nephew [10-20]% plus Centerpulse [5-15]%), and France [20-30]% (Smith & Nephew [5-15]% plus Centerpulse [15-25]%).
20. Despite the leadership that the new entity resulting from the merger will acquire in a number of countries, the parties claim that these markets will remain competitive because of the presence of several large competitors active in Europe such as Johnson & Johnson/Depuy, Stryker, Zimmer, and others. Furthermore, the parties refer to other considerations militating in favour of a competitive environment, such as the wide use of tendering mechanisms, the increasing formation of buyer groups, the consistent growth of the industry over the last years, the expansion by existing players into new products and countries and the absence of significant entry barriers (in terms of establishment and transport costs, distribution networks, patents, R&D, length of exclusive contracts).
21. The results of the market investigation have confirmed the competitiveness of the affected markets post-transaction, due to the following considerations :
  - (a) The presence of a sufficient number of competitors on the various national markets concerned by the operation, particularly some large manufacturers which are in a position to reasonably contest the leadership to be acquired in some of those markets by the new entity (i.e. Johnson & Johnson/Depuy, Stryker, Zimmer and Biomet). Furthermore, it is to be noted that the merging parties are not regarded by most customers as close competitors, but as competing players which are largely complementary in terms of product lines and geographic presence .
  - (b) The ability of manufacturers to offer a full range of products plays an important role in terms of procurement, but it is not a determinant factor to customers. The quality and the long-term results (clinical evidence) of the product are the key criteria for selection. In particular, from the market investigation it appears that hospitals have an interest in principle to work with a supplier capable of providing a wide range of implants and other orthopaedic products. However, they do not tend to procure as a matter of rule a package of replacement joints from one single supplier through comprehensive tenders. Rather, tenders are often organised for single items, and dual if not multiple sourcing supplies are also a usual practice. As a consequence, the fact to be able to market a

wider range of implants as a result of the merger would give the merging entity a limited competitive advantage, both because there is limited interest for the demand to procure from one source and because most suppliers can already match the parties' strategy by offering as well a full range of implants. In sum, according to the market investigation, the complementary nature of the merging parties will allow the new entity to develop and market a wider range of improved products, but will not result in a significant increase of market power in any of the affected markets, given the presence of a number of players which are in a position to offer satisfactory alternatives, and the purchasing patterns characterising the demand in this sector.

- (c) SN currently holds patents over certain technologies related to reconstructive devices, and the Commission has carefully examined to what extent these proprietary technologies, in particular the so-called oxinium technology, could give rise to competition concerns in the affected markets. Oxinium is the brand name for oxidised zirconium, a metallic alloy-based material used in hip and knee products in order to improve their longevity. According to the information provided in the course of the Commission's market investigation, only oxinium products for knee are currently available in Europe, sales being limited to less than [0-10]% of total knee units sold. Oxinium devices were launched in the US (year 2001) as a competitive response to a number of existing low wear alternatives. Indeed, all major manufacturers dispose of the capability to develop competing technologies and have done so, including Centerpulse. Furthermore, in the industry for reconstructive implants clinical evidence and long-term results are decisive factors for market penetration of new products, which is typically very gradual in nature. Against this background, it can be concluded that significant competitive concerns can be discarded since the oxinium technology, although potentially promising, is currently in its infancy and a rapid adoption cannot be anticipated.

## V. CONCLUSION

22. For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of Council Regulation (EEC) No 4064/89.

For the Commission  
(*Signed*)  
Mario MONTI  
Member of the Commission