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(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 25 August 2005

declaring a concentration compatible with the common market and the functioning of the EEA Agreement

(Case COMP/M.3687 — Johnson & Johnson/Guidant)

(notified under document number C(2005) 3230)

(Only the English text is authentic)

(Text with EEA relevance)

(2006/430/EC)

On 25 August 2005 the Commission adopted a Decision in a merger case pursuant to Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings [1], and in particular Article 8(1) of that Regulation. A non-confidential version of the full Decision can be found in the authentic language of the case and in the working languages of the Commission on the website of the Directorate-General for Competition, at the following address: http://europa.eu.int/comm/competition/index_en.html

I. INTRODUCTION

(1) On 15 March 2005, the Commission received a notification of a proposed concentration pursuant to Article 4 of Regulation (EC) No 139/2004 (Merger Regulation) by which the undertaking Johnson & Johnson (J & J, USA) acquires within the meaning of Article 3(1)(b) of that Regulation control of the whole of the undertaking Guidant Corporation (Guidant, USA) by way of purchase of shares.

A. The Parties

(2) J & J is a company incorporated in the USA. In 2003, it had 111 000 employees worldwide and generated a turnover of around EUR 37 billion. Its activities span over three main businesses: consumer goods (18 % of turnover), pharmaceuticals (47 %) and medical devices and diagnostics (MD & D, 36 % of turnover).

(3) Guidant is a company incorporated in the United States of America (USA) that is active in the design and development of cardiovascular medical products. In 2003, it had around 12 000 employees worldwide and a turnover of around EUR 3,3 billion. Guidant's presence covers four main areas within the fast-growing cardiovascular medical products business: cardiac rhythm management, interventional cardiology, endovascular devices and cardiac surgery.

B. The operation

(4) The concentration is an acquisition of sole control by J & J over Guidant, within the meaning of Article 3(1)(b) of the EC Merger Regulation.

II. THE RELEVANT MARKETS

(5) The market investigation confirmed that the areas mostly affected by the merger are the following: 1. interventional cardiology devices; 2. endovascular devices; 3. cardiac surgery devices; and 4. cardiac rhythm management devices. In the latter, there are no overlaps, as J & J is currently not active in the business.

[1] OJ L 24, 29.1.2004, p. 1.

A. **The relevant product markets**

1. *Interventional cardiology devices*

(6) Interventional cardiology devices are designed to treat, through minimally invasive procedures, coronary artery diseases. In this area the main device is the stent, a small expandable wire tube that is placed in an occluded coronary artery to remove the plaque and support the walls of the vessel, thus enabling the blood to flow properly.

(7) Bare metal stents (BMS) and drug eluting stents (DES) are two separate product markets for the following reasons: no significant price correlation, no supply side substitutability, very significant differences in clinical outcomes, and different reimbursement systems. Moreover, despite the fact that BMS and DES share the same stent structure and delivery system, a number of components are specifically important to a coronary DES (the drug, drug dosage and rate of release, and polymer coatings).

(8) Concerning the accessories coronary guiding catheters, coronary steerable guidewires, coronary PTCA balloon catheters, the Commission's market inquiry has established that each of these products constitutes a separate relevant product market. Most interventions will require a specific set of accessories, with different dimensions and shape.

2. *Endovascular devices*

(9) Endovascular devices are used for the minimally invasive treatment of peripheral vascular (or endovascular) diseases such as the build up of plaque (i.e. vessel calcification) in peripheral vessels (peripheral arterial disease) and aneurysm (the enlargement of a weak area of an artery).

(10) Similar to interventional cardiology stents, endovascular stents are small expandable tubes designed to treat a narrowing or blockage in a peripheral artery.

(11) The parties submitted, and the Commission's market inquiry confirmed, that two separate markets should be identified for endovascular stents: a market for balloon expandable stents (BX) (usually made of stainless steel and which come mounted on a PTA balloon catheter), and a market for self-expandable stents (SX), which use a different deployment technology. The Commission inquiry established a clear trend towards more specialisation in the endovascular area, both for BX stents (e.g. segments for renal (BX) stents and for iliac-femoral (BX) stents) and for SX stents (e.g. segments for femoral (SX) stents, iliac (SX) stents and carotid stents).

(12) As far as the accessories are concerned, endovascular guiding catheters, steerable guidewires and PTA balloon catheters perform a similar function to the corresponding products in interventional cardiology. Similarly to the coronary area, a relevant market should be defined for each of these accessories, due to the high degree of supply side substitutability and the fact that all major manufacturers offer, within each accessory, a very broad range of models in terms of dimensions and shapes.

3. *Cardiac surgery devices*

(13) Coronary artery bypass graft surgery (CABG) is used to treat coronary artery disease; the blocked artery is 'bypassed' by sewing (grafting) another blood vessel to the aorta at one end and to the coronary artery beyond the damaged area the other end. After the operation, blood flows through the new grafted vessel to the heart muscle. The vessel used for the bypass is removed (harvested) from the leg (saphenous vein graft), chest or arm.

(14) The following markets are affected in the cardiac surgery area: (i) beating-heart CABG products (stabilisation systems and accessories as blowers/misters); and (ii) endoscopic vessel harvesting (EVH) devices.

B. **The relevant geographic markets**

(15) The market investigation confirmed that relevant geographic markets are all national because of significant differences between reimbursement schemes and procurement processes; price variations between countries; need to establish a local sales office; the parties' and competitors' market share variations across Member States.

III. **COMPETITIVE ASSESSMENT**

A. **Interventional cardiology**

(16) Interventional cardiology is a relatively recent, innovation driven business which is characterised by significant barriers to entry, i.e. R & D financing, intellectual property rights for product development, long time-to-market for new products, clinical trials, and product range.

(17) In the area of interventional cardiology there are two leagues of players: large global companies competing on a worldwide level (J & J, Guidant, Medtronic, Boston Scientific and Abbott) and 'local players' (Sorin, Biotronik and others).

1. *Drug-eluting stents*

(18) In the market for DES, the concentration would result in the removal of a potential competitor given that Guidant is present only in BMS and not yet in DES, while J & J is one of the only two players already active in this segment, the other being Boston Scientific.

(19) Despite the fact that there is an indication that Guidant would likely have been one of the key players in the market for DES, acting as a major competitive constraint *vis-à-vis* the two current competitors J & J and Boston Scientific, the evidence collected in the investigation also proved that the other new entrants will be likely to exert sufficient competitive constraints on the market for DES, compensating for the loss of competition resulting from J & J's acquisition of Guidant (Medtronic, Abbott, Conor/Biotronik and Sorin).

(20) The Commission, therefore, concluded that the notified concentration does not raise any serious doubts as to its compatibility with the common market with regard to DES and thus, the concentration will not significantly impede effective competition in the common market for DES.

2. *Steerable guidewires*

(21) In the interventional cardiology market for steerable guidewires virtually all national markets are strongly affected by the concentration (above 40 % and with an increment of at least 5 %), and in many of these, including the largest countries of the EU, the parties' combined market shares are above (65 to 75 %) and even (75 to 85 %).

3. *Conclusion*

(22) The Commission, therefore, concluded that the notified concentration raises serious doubts as to its compatibility with the common market by enabling the merging parties to strengthen Guidant's uncontested leadership, in so far as it removes one of the only two main competitors in this market. Further, the remaining firms in the market may even be expected to benefit from the reduction in competition which will result from the merger; the increase in concentration will enable them to attain higher prices than would otherwise have been the case.

B. **Endovascular devices**

(23) Both J & J and Guidant are leading suppliers in the area of endovascular devices in the EEA. Although there is a fair number of competitors in the endovascular markets (Abbott, Bard, Boston Scientific, B.Braun, Cook, Edwards Lifesciences, ev3, Invatec, Medtronic, Sorin and Terumo), not all players have the same strength or are present in all product or geographic markets. Moreover, the market investigation has highlighted that the disappearance of Guidant as a competitor will eliminate the closest substitute to J & J stents.

(24) In the endovascular market for balloon expandable stents, at EEA level, the combined market share of the merging parties amounts to (60 to 70 %), (J & J, (30 to 40 %), Guidant, (25 to 35 %)). Those market shares have been relatively stable for the past four years.

(25) When looking at the relevant geographic markets, i.e. each Member State, for the purpose of the competitive assessment, there are nine countries more substantially affected, namely: Austria, Belgium, France, Germany, Italy, Luxembourg, Netherlands, Portugal and Spain.

(26) Having regard to the fact that the merger combines the strongest and second strongest player, it will create a dominant position in virtually all the markets considered and will lead to a significant impediment to effective competition.

(27) In the endovascular market for Carotid stents in the EEA, the member States most substantially affected are: Austria, Belgium, Finland, France, Germany, Italy, the Netherlands, Portugal and Spain.

(28) There are three main players in the carotid stent market: J & J, Guidant and Boston Scientific. Together they account for 83 to 96 % of the market. The concentration will either reinforce the leadership of J & J or Guidant (in Austria, Finland, the Netherlands, Portugal and Spain) or combine the second and third player to create a new market leader (Belgium, Germany and Italy).

(29) In the above national markets, given the degree of concentration, barriers to entry, customer loyalty, closeness of substitution and, as a result of the elimination of a major competitive constraint, the operation will give rise to unilateral adverse effects in those markets and therefore impede effective competition in the common market.

(30) In the endovascular devices market for non-carotid stents, the Member States most substantially affected are: Austria, Belgium, Germany and the Netherlands. In most of these markets, J & J is market leader and Guidant is one of the leading players and is considered by the majority of the customers as the closest substitute to J & J.

(31) With regard to non-carotid SX stents in the above national markets, the concentration will give rise to non-coordinated adverse effects in those national markets and therefore impede effective competition in the common market and the EEA as a result of the creation or strengthening of a dominant position.

(32) The Commission, therefore, concluded that the notified concentration raises serious doubts as to its compatibility with the common market with regard to endovascular stents market. The concentration will create a dominant position in balloon expandable stents market and will give rise to unilateral adverse effects in carotid and non-carotid stents markets and therefore will impede effective competition in the common market.

C. **Cardiac surgery: endoscopic vessel harvesting systems**

(33) The EEA sales of EVH systems are significantly lower than in the United States but show a growing trend. In Europe, traditional vessel harvesting is used in the large majority (98 %) of procedures. J & J and Guidant are virtually the only two suppliers of EVH systems, with market shares estimated at 90 to 95 % by the parties and 100 % by market players across Europe.

(34) The Commission, therefore, concluded that the notified concentration raises serious doubts as to its compatibility with the common market with regard to the EVH systems and will result in creation of a virtual monopoly across Europe.

IV. **COMMITMENTS OFFERED BY THE PARTIES**

(35) In order to address the aforementioned competition concerns in the steerable guidewires, the endovascular and the cardiac surgery markets, the Parties submitted the undertakings described below:

(a) in the steerable guidewires business, the parties propose to divest the assets associated predominantly with the supply, marketing and sale of J & J steerable guidewires business in the EEA. In essence, the divestiture would consist of the transfer of the inventory and the customer list, the assignment of rights for use of trademarks, the licence of IP rights, the transfer of specifications relating to the design of J & J guidewires. The divestment has a field of use limited to Europe and does not include manufacturing, assembly, sterilisation (these operations are currently outsourced by J & J to a third party), distribution and warehousing;

(b) in the endovascular area, the parties have proposed to divest the entire operations (products, logistics, inventory, customer list, sales force, brand names, and intellectual property) of Guidant's endovascular solutions business in the EEA. The divestment does not include manufacturing, finance, administration, R & D, regulatory, quality and clinical research teams, which are based in the USA and operate on a worldwide basis. The parties offer to the purchaser an interim OEM supply agreement followed by either the continuation of such agreement or the full assistance to replicate the USA production facility in Europe. The divestment also includes embolic protection devices and endovascular accessories on top of the endovascular stents on which the Commission's analysis was focused;

(c) for the cardiac surgery area, the parties have proposed to divest alternatively either:

(a) J & J's endoscopic vessel harvesting products (EVH) and endoscopic radial artery harvesting (ERA kits); or

(b) GDT worldwide assets and personnel of cardiac surgery business division; or

(c) Guidant's endoscopic vessel harvesting products, namely procedural kits for EVH (EVH kits).

V. **ASSESSMENT OF THE COMMITMENTS SUBMITTED**

(36) As confirmed by the results of the market test conducted by the Commission, these undertakings can be considered sufficient to properly remedy the competition concerns in the steerable guidewires, the endovascular and the cardiac surgery markets, as outlined above.

(37) The Commission, therefore, reached the conclusion that, on the basis of the commitments submitted by the Parties, the notified concentration will not significantly impede effective competition, in the common market or in a substantial part of it. Consequently, the Decision suggests declaring the concentration compatible with the common market and the EEA Agreement, in accordance with Articles 2(2) and 8(2) of the Merger Regulation and Article 57 of the EEA Agreement.

VI. **CONCLUSION**

(38) For the reasons set out above, the Commission concluded that the proposed concentration does not significantly impede effective competition in the common market or a substantial part of it. The concentration was therefore declared compatible with the common market and the EEA Agreement in a decision on 25 August 2005, in accordance with Article 8(1) of the Merger Regulation and Article 57 of the EEA Agreement.