EN

Case No COMP/M.3687 – JOHNSON&JOHNSON / GUIDANT

Only the English text is authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 8 (2)
Date: 25/08/2005

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25.08.2005

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PUBLIC VERSION

COMMISSION DECISION

of 25/08/2005

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

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Agreement on the European Economic Area, and in particular Article 57 (2)(a) thereof,

Having regard to Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings[1], and in particular Article 8(2) thereof,

Having regard to the Commission's decision of 22 April 2005 to initiate proceedings in this case,

Having given the undertakings concerned the opportunity to make known their views on the objections raised by the Commission,

Having regard to the opinion of the Advisory Committee on Concentrations,

Having regard to the final report of the Hearing Officer in this case,

WHEREAS:

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 ("the Merger Regulation") by which the undertaking Johnson&Johnson ("J&J"), of the USA, would acquire, within

1 OJ L 24, 29.1.2004, p. 1

the meaning of Article 3(1) of the Merger Regulation control of the whole of the undertaking Guidant Corporation ("Guidant"), of the USA, by way of a purchase of shares.

2. On 22 April 2005, having examined the notification, the Commission concluded that the notified operation fell within the scope of the Merger Regulation and that it raised serious doubts as to its compatibility with the common market and with the EEA Agreement. The Commission therefore initiated proceedings in accordance with Article 6(1)(c) of the Merger Regulation and Article 57 of the EEA Agreement.

II. THE PARTIES

3. J&J is a company incorporated in the USA. In 2003 it had 111,000 employees worldwide and generated a turnover of around € 37 billion (of which approximately € […]* billion arose in Europe). Its activities span three main businesses: consumer goods (18% of turnover), pharmaceuticals (47%) and medical devices and diagnostics ("MD&D", 36% of turnover). Within MD&D, J&J's cardiovascular businesses belong to the Cordis franchise and the Ethicon franchise (both J&J wholly owned subsidiaries). The Cordis franchise manufactures and sells devices for minimally-invasive vascular disease management. Cordis has four business units: (i) Cordis Cardiology; (ii) Cordis Endovascular; (iii) Cordis Neurovascular; and (iv) Biosense Webster. Within the Ethicon franchise, the CardioVations division develops, manufactures and sells products for less invasive cardiac surgery procedures.

4. Guidant is a company incorporated in the USA that is active in the design and development of cardiovascular medical products. Guidant was funded in 1994 from a spin-off from the pharmaceutical company Eli Lilly. In 2003 it had around 12,000 employees worldwide and a turnover of around € 3.3 billion (approximately € […]* million in Europe). 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.

III. CONCENTRATION

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

6. J&J intends to acquire all of the outstanding voting securities of Guidant. The acquisition will be accomplished through a reverse triangular merger, whereby Shelby Merger Sub, Inc., a subsidiary of J&J specifically set up for this purpose, will be merged into Guidant, with Guidant surviving as a wholly-owned subsidiary of J&J. As a result of the merger, each share of issued and outstanding Guidant common stock will be converted into the right to receive 40% cash and 60% J&J common stock. No public tender offer will take place.

* Parts of this text have been edited to ensure that confidential information is not disclosed; those parts are enclosed in square brackets and marked with an asterisk.

IV. COMMUNITY DIMENSION

7. The undertakings concerned have a combined aggregate world-wide turnover of more than € 5 billion[2]. J&J and Guidant each have a Community-wide turnover in excess of € 250 million, but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The notified operation therefore has a Community dimension.

V. RELEVANT MARKETS

A. RELEVANT PRODUCT MARKETS

8. The transaction involves four main areas within the cardiovascular medical products business: i) interventional cardiology devices; ii) endovascular devices; iii) cardiac surgery devices; iv) cardiac rhythm management devices. In each of these areas, a number of product markets are concerned.

1) Interventional cardiology devices

9. Interventional cardiology is a field of heart medicine dedicated to research and technology for minimally invasive procedures to treat Coronary Artery Diseases. These procedures include the dilatation of narrowed or blocked coronary blood vessels using a balloon catheter and often a stent, which is inserted into the cardiovascular system via an artery most often using the groin as an entry point. The interventional cardiologist uses x-rays and other imaging devices to guide thin catheters and other small tools through the body to the heart to treat diseased arteries of the heart without surgery.

10. The parties submit that the following markets are affected in the interventional cardiology devices area: Guiding Catheters; Steerable Guidewires ("SGW"), PTCA (meaning Percutaneous Transluminal Coronary Angioplasty) balloon catheters, and Bare Metal Stents ("BMS"). Additionally, the parties submit that the operation may have a significant impact in the distinct market for Drug-Eluting Stents ("DES"), where Guidant is not currently present but is a potential entrant. These products are described below. Finally, the parties have reported minimal overlaps in some accessories used in interventional cardiology procedures, namely haemostasis valves, balloon inflation devices, and guidewire torquing devices. In view of the very small overlaps in these markets (approximately 2% in the EEA), they will not be considered in the following.

(a) Coronary Bare Metal Stents (BMS) and Drug Eluting Stents (DES)

11. A stent is a small expandable wire tube that is used to support the walls of the coronary artery following an angioplasty procedure. The stent is usually premounted on the balloon so that when the balloon is inflated the stent expands to fit the inner wall of the vessel. The balloon is then deflated and withdrawn; while the stent stays in place permanently (the metal structure is in time covered with artery tissue). Stenting represents an improvement over simple angioplasty in that it significantly reduces the risk of collapse of the artery walls following the procedure.

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[2] Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Notice on the calculation of turnover (OJ C 66, 2.3.1998, p 25).

12. The parties submit that the market for stents should be extended to include both the stent proper (i.e. the expandable wire tube) and the delivery system for its placement, which is basically a PTCA balloon catheter. According to the parties, the two components are always sold as a system (among others for safety reasons). Furthermore, the characteristics and the value of the system is largely determined by the wire tube part, while the rest of the system is a more homogeneous product[3]. The investigation has confirmed that the stent is generally sold together with its delivery system. For these reasons, in the following the word 'stent' will be used to denote the complete system, which includes the delivery method.

13. The parties submit that two separate product markets for stents exist: BMS and DES. DES are a recent[4] evolution of BMS, whereby a drug and a drug-releasing mechanism is added to the basic expandable wire tube. The main advantage of DES over BMS is that it reduces restenosis (excessive cell growth within and near the stented area, probably as a response to the trauma caused by the inflation of the balloon) through the gradual release of the drug. This, in turn, reduces the likelihood that a repeat intervention will be necessary to re-widen the area for blood flow.

14. BMS and DES share the same stent structure and delivery system. These common elements determine some important characteristics of the product, as deliverability (how well the interventional cardiologist is able to manoeuvre through tortuous anatomies and reach more difficult lesions), conformability (how well the stent preserves its shape independently of the target vessel shape) and radiopacity (the 'visibility' of the stent using X-ray or fluoroscopy).

15. In DES, the bare metal structure is usually coated with a polymer and a drug[5]. The polymer can serve either as the mechanism for carrying the drug or as the mechanism to control the release of the drug in the target area. A number of components are specifically important to a coronary DES, and chiefly:

    (a) The drug: two drugs are currently used in the main DES on the market, sirolimus (rapamycin) by J&J and Paclitaxel (Taxol) by Boston Scientific. The former is a immunodepressant with antiproliferative effects, while the latter is a microtubule stabiliser that inhibits cell proliferation. Drugs of the same family as sirolimus are being tested by potential DES entrants Guidant, Medtronic and Abbott, while potential entrant Conor Medsystems is testing a DES with Paclitaxel.

    (b) Drug dosage and rate of release: they determine how much drug is absorbed by the vessel over time. While too little could lead to sub-optimal effects, too much can result in compromised safety.

    (c) Polymer coatings: are mostly used to control the rate of drug release. There are various types of polymer coatings in use or being tested, both permanent and bioerodable. Some companies apply a non-polymeric coating to their stents.

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3 At least in the EEA, where the RX delivery system has become a standard.

4 The first DES, J&J's Cypher, was marketed in Europe in 2002 and in the USA in 2003.

5 An alternative method is to carve micro reservoirs in the stent structure, to be filled with the drug.

16. Since coronary stents are very delicate devices used to treat life threatening conditions, regulatory approval in Europe, as well as in other jurisdictions, is subject to particularly strict rules. Under Community rules[6], they are classified as Class III[7] products, which require a substantive body of clinical investigation in order to obtain regulatory approval (CE Mark in Europe). Furthermore, as DES incorporate a pharmaceutical component, an additional approval process is required to verify the safety, quality and usefulness of the medicinal product.

17. The following elements point towards the existence of separate product markets for BMS and DES:

(a) While both use the same stent platform and delivery system, the drug and drug release components are complex elements that exclude supply side substitutability. While BMS expertise is necessary to produce DES, it is by no means sufficient. Additional investments in terms of R&D, manufacturing and approval by regulatory agencies are required.

(b) DES bring significant clinical improvements over BMS, in particular reduced restenosis rates. This has led interventional cardiologists to use DES to treat a larger number of lesions in a larger patient population (more difficult lesions, more complex clinical situations) as compared to BMS.

(c) DES sell at a very substantial price premium over BMS (in 2003, the average sales price for a BMS was € […]* in the EEA, against € […]* for DES). While both products have shown a declining price trend over time, the trends are not correlated. In particular, the price of J&J's Cypher DES was not constrained by BMS price after its European launch in 2002. Conversely, the introduction of a rival DES by competitor Boston Scientific in 2003 led to a significant reduction in prices.

(d) DES are destined to completely replace BMS in all instances in which restenosis is a concern. BMS are predicted to either exit the market as a stand-alone product, or to be limited to those interventions for which restenosis is not an issue (large vessels).

(e) In some European countries, more expensive DES are not reimbursed by the health agencies, are reimbursed only in part or are reimbursed only for very specific applications. In these instances, DES cannot be used as substitutes for BMS.

(f) Crucially, as the parties have demonstrated in the course of the second phase investigation by providing a market study conducted before the merger and a correlation analysis study, there is no significant price correlation between BMS and DES in the European markets.

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6 The reference Directives are: Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L 189, 20.7.1990, p. 17, as last amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1); Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1, as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284 , 31.10.2003, p. 1); and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ L 331, 7.12.1998, p. 1, as last amended by Regulation (EC) No 1882/2003.

7 All implantable devices and long-term surgically invasive devices are in Class IIB, unless they are intended to be used in direct contact with the heart, the "central circulatory system" or the central nervous system, in which case they are designated as Class III products.

18. In the course of the Commission's market inquiry, some elements were brought to the Commission's attention indicating that BMS and DES may be considered to constitute a single product market:

(a) BMS and DES treat the same human conditions and are used by interventional cardiologists in very similar procedures, there are no alternatives to BMS and DES;

(b) They share the same implant delivery system, technique, and manufacturing systems, except for the drug coating of the DES;

(c) Drug elution is not the only element of choice for a stent. Other characteristics (such as deliverability, radiopacity, etc.) determine the cardiologists' choice. Therefore, a doctor may decide to use a BMS instead of a DES because it performs better along one of the relevant factors of choice. This factor will lose importance as more DES models enter the market, but is currently still relevant.

(d) For some procedures, BMS and DES are currently considered interchangeable[8]. It is possible that further clinical research will reduce the areas of overlap, but this is not the case yet.

19. These elements are, however, not sufficient to prove that BMS and DES belong to the same product market: as was noted above, the manufacturing differences between the two are substantial, even if part of the process is common; the therapeutic effects are different to the extent only the DES aims at treating the restenosis while the BMS does not; the preference of some doctors of BMS over DES does not imply substitutability, but once again points to different markets; finally, the number of procedures where BMS and DES are considered interchangeable is limited, and is constantly reduced by new evidence on the benefits of DES.

20. In light of the above, it can be concluded that BMS and DES constitute separate product markets.

(b) The accessories

(1) Coronary Guiding Catheters

21. A guiding catheter is a long, hollow tube manufactured from a polymer blend that is inserted into the radial or femoral artery and is advanced to the origin of the coronary arteries. Its purpose is to allow the other devices (including SGW, PTCA balloon catheters and stents) to reach the site of the lesion in the coronary artery. It is also used as a way to inject contrast medium during the procedure, allowing the interventional cardiologist to monitor the position of the devices and the lesion using X-ray or fluoroscopy.

22. According to the parties, guiding catheters are sold in a range of dimensions, shapes and curvatures, in order to facilitate treatment in different coronary arteries and anatomy of patients. This means that most interventions will require a specific guiding catheter, which cannot be substituted by another with different dimensions and shape. Thus, demand substitution is limited between the different models. However, all suppliers offer a wide range of models in terms of dimensions and shapes. All dimension and

8 For example, the exact definition of a 'large vessel' varies according to different respondents. This means that for some intermediate vessel sizes both BMS and DES are considered valid devices.

shapes are manufactured using the same technology and there is a high degree of supply side substitutability between them. For these reasons, all guiding catheters can be considered to belong to the same relevant market.

23. The Commission's market inquiry has confirmed this conclusion. Except for a few suppliers offering guiding catheters with very particular specifications in terms of dimensions and shapes, all types are widely available from a number of competitors. Although niche products exist and cardiologists' preferences may play a role in the choice of a specific brand or model, by and large guiding catheters were considered fairly homogeneous products by the majority or respondents.

24. Conversely, the Commission market inquiry has indicated that coronary guiding catheters are in different product markets than endovascular guiding catheters (please see below the section on endovascular devices for a discussion on this point).

25. Based on the above, the Commission concludes that guiding catheters for interventional cardiology form a relevant product market.

(2) Coronary Steerable Guidewires

26. A SGW is a very thin and flexible wire which is advanced though the guiding catheter beyond the narrowed area of the artery which requires dilatation. SGWs are typically made of an inner core, an outer covering and a coating. The combination of these elements determines the characteristics of the SGW in terms of manoeuvrability, ability to reach beyond the lesion and deliverability. As guiding catheters, SGWs are available in a range of dimensions and shapes.

27. According to the parties, and similarly to guiding catheters, all coronary SGWs should be included in the same relevant market taking into consideration the high degree of supply side substitutability between different types and the fact that all major manufacturers offer a very broad range of products in terms of dimensions and shapes.

28. This conclusion is supported by the Commission's market inquiry. Although niche products exist cardiologists' preferences may play a role in the choice of a specific brand or model, coronary SGWs were considered fairly homogeneous by the majority or respondents. Conversely, the Commission market inquiry has indicated that coronary SGWs are in different product markets than endovascular SGW: see the section on endovascular devices (paragraphs 34 to 54) for a discussion on this point.

29. On the basis of the above, the Commission concludes that steerable guidewires for interventional cardiology form a relevant product market.

(3) Coronary PTCA Balloon Catheters

30. A PTCA balloon catheter is a long, flexible, hollow tube with a balloon at the end. It is inserted in the guiding catheter and is advanced to the occluded vessel using the steerable guidewire as a lead. Once the lesion site has been reached, the balloon is inflated a number of times to compress the plaque against the arterial wall, widening the area for blood flow. This procedure is called angioplasty and does not involve the placement of a stent.

31. PTCA balloon catheters are sold in a wide range of dimensions and types, and differ inter alia with respect to delivery system, tip softness, shaft flexibility, ease of pushing and balloon folding technology. As for the delivery system, in the past ten years the Rapid Exchange (hereinafter "RX") delivery system has become a standard in the EEA, and is currently mounted on the great majority of the PTCA balloon catheters sold. With the RX system, the PTCA balloon catheter slides on only a small part of the steerable guidewire (5 to 30cm)[9] to reach the target vessel, improving manoeuvrability and safety of the intervention.

32. According to the parties, and similarly to guiding catheters and steerable guidewires, all PTCA balloon catheters should be included in the same relevant market taking into consideration the high degree of supply side substitutability between different types and the fact that all major manufacturers offer a very broad range of products in terms of dimensions and shapes. This conclusion was supported by the Commission's market inquiry. Although niche products exist and cardiologists' preferences may play a role in the choice of a specific brand or model, PTCA balloon catheters were considered fairly homogeneous by the majority of respondents. Conversely, the Commission market inquiry has indicated that PTCA balloon catheters are in different product markets than their endovascular corresponding product (please see below the section on endovascular devices for a discussion on this point).

33. Based on the above, the Commission concludes that PTCA balloon catheters for interventional cardiology form a relevant product market.

2) Endovascular devices

34. Endovascular devices are used for the minimally invasive treatment of peripheral vascular (or endovascular) diseases. These include 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). Although less likely to be life threatening than coronary artery diseases, endovascular diseases have a life-limiting impact on patients.

35. Peripheral Arterial Disease is often used to define stenotic disease in arteries other than the coronary arteries. In particular, build-up of plaque occurs relatively frequently in one or more of the following peripheral arteries: (i) the carotid arteries (the main arteries in the head and neck that supply blood to the brain); (ii) the arterial branches that supply the kidneys (renal arteries); (iii) the part of the aorta that passes through the abdomen (abdominal aorta) or in its branches, including the lower aorta where it divides into two branches, called the iliac arteries, which supply blood to the lower abdomen and the legs; (iv) the arteries of the legs, including the main arteries of the thighs (femoral arteries), the knees (popliteal arteries) and the distal part of the legs (tibial and peroeal arteries, or below-the-knee).

36. The endovascular treatment of Peripheral Arterial Disease is similar to that for Coronary Artery Disease. The procedures involve using a balloon catheter and often a stent, which is inserted into the cardiovascular system via an artery. Three types of physicians normally carry out these procedures: interventional radiologists (50-60% of procedures in Europe), vascular surgeons (20-30%) and interventional cardiologists (10-15%).

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9 With the previous system, called Over The Wire ("OTW"), the PTCA balloon catheter would be inserted over the whole length of the steerable guidewire.

37. The parties submit that the following markets are affected in the endovascular devices area: Guiding Catheters, Steerable Guidewires ("SGW")[10], PTA (meaning Percutaneous Transluminal Angioplasty) balloon catheters, Balloon Expandable stents ("BX"), Self Expandable stents ("SX"), and Embolic Protection Devices ("EPD"). The products are described below.

(a) Endovascular Stents

38. Similarly to interventional cardiology stents, endovascular stents are small expandable tubes designed to treat a narrowing or blockage in a peripheral artery. Although research is ongoing in this area, currently there are no drug eluting stents for endovascular procedures.

39. The parties submit that two separate markets should be identified for endovascular stents: a market for BX stents, and a market for SX stents. BX stents, usually made of stainless steel, are similar to BMS for interventional cardiology, and come mounted on a PTA balloon catheter[11]. On the contrary, SX stents use a different deployment technology: the SX stent is placed on a plain catheter (without balloon) and covered by a protective sheath. Once in place, the sheath is rolled back by the physician and the stent expands to fit the artery. Most SX stents are made of nitinol, an alloy with shape memory properties. These properties ensure the correct expansion of the stent in the artery, and make SX stents particularly apt for superficial arteries subject to mechanical forces. The parties have also provided market separate data for carotid stents, which are of the SX stent type.

40. The Commission's market inquiry has confirmed that separate markets for BX and SX stents exist. Firstly, the stents are used predominantly for different applications: BX stents have a penetration rate close to 100% in renal procedures; SX stents have a 100% penetration rate in carotid procedures and are predominantly used for femoral, popliteal and tibial and peroneal arteries[12]. In iliac procedures both BX and SX stents are used, and the market inquiry has indicated a certain degree of substitutability between them[13]. However, even for iliac procedures, respondents who have provided a more detailed analysis[14] stressed that the choice between SX and BX stents is dictated by the characteristics of the individual lesion to be treated. For example, BX stents are preferred for more calcified lesions due to their higher strength in breaking the plaque that covers the arteries, while SX stents are favoured for placement in areas subject to contraction and torsion, thanks to their superior flexibility and capacity to return to their

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10 The parties point out that the market for endovascular SGWs is not affected at EU or EEA level. However, it is an affected market at national level for some MSs.

11 The delivery system is however often different. While RX is the standard in Europe for coronary stents, BX often uses OTW delivery systems.

12 See responses to questions 5 and 6 of the Commission's Article 11 letter dated 16.3.2005 addressed to customers of endovascular devices.

13 See for example responses with folio numbers 5947 dated 29.3.2005, 8540 dated 13.5.2005, to the Commission's Article 11 letter dated 16.3.2005 addressed to customers (questions 5 and 6).

14 See for example responses with folio numbers 5956 dated 29.3.2005, 6067 dated 30.3.2005, 5861 dated 29.3.2005, 57030 dated 23.3.2005 to the Commission's Article 11 letter dated 16.3.2005 addressed to customers of endovascular devices (questions 5 and 6). See also summary of conference call with Prof. Biamino, folio number 11550 dated 17.6.2005.

original shape. Therefore, the degree of substitutability between BX and SX stents is very limited also for iliac procedures.

41. Secondly, SX stents are considerably more expensive than BX stents (something in the range of 20-30%). Finally, there is very limited supply side substitutability between BX and SX stents: they have different design, they are made of different materials, they use different deployment techniques and they require different manufacturing processes (e.g. the production process is lengthier for SX stents), skills and competences.

42. Within the SX stents, a separate market for carotid stents should be defined. While most endovascular stents are Class IIB products for regulatory approval purposes, carotid stents are Class III products (the same class as coronary stents). This implies that a carotid stent must undergo a specific approval process that is not shared by any other endovascular stent. As a consequence, no other stent can be marketed as a carotid stent, and stents designed for carotid applications are usually not used for any other procedure. Suppliers produce and market stents dedicated to carotid procedures (e.g. Guidant's Acculink, J&J's Precice, Boston Scientific's WallStent). Physicians consider carotid stents as different from any other type of stents[15] and use dedicated stents only for carotid procedures. There is therefore neither demand-side nor supply-side substitutability between carotid and other endovascular stents.

43. The situation is somewhat different for other, non carotid, endovascular stents (both BX and SX). As mentioned above, these devices undergo a lighter (class IIB) approval process than carotid stents. They normally receive CE marking for generic endovascular use[16]. In the past, this was matched by the use of the same type of stents for different procedures. For this reason, the parties hold the view that it is not possible to distinguish separate markets according to the type of procedure for which the stents are used[17]. On the contrary, a number of competitors claim that different markets should be defined according to the specific procedure the stents are used for[18].

44. The Commission inquiry has established a clear trend towards more specialisation in the endovascular area, with a growing number of stents being dedicated to specific procedures. This is chiefly because there is growing awareness in the medical community that the lesions in different peripheral locations present significantly different characteristics and require specifically designed stents to be treated in an efficacious way[19]. This trend is being progressively endorsed by the suppliers, who are

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15 See responses to question 9 of the Commission's Article 11 letter dated 16.3.2005 addressed to customers of endovascular devices.

16 In the US, they are normally approved for biliary procedures (to prevent the backflow of bile and other material from the bile duct to the bloodstream) and subsequently used for endovascular procedures as well.

17 See Form CO p. 260 on and the memorandum from the parties dated 24.5.2005, in response to the Commission information request dated 17.5.2005, question 10. The parties state that there is no possibility to know which stents are used in which procedure. They therefore provide a rough estimation of market shares based on the diameter of the stent (since the renal and femoral arteries are smaller than the iliac arteries).

18 See response of Abbott with folio number 9359 dated 27.5.2005, response of Medtronic with folio number 6101 dated 30.5.2005, response of Sorin folio number 8136 of 4.5.2005 to the Commission's Article 11 letter dated 17.3.2005 (question 2).

19 See summary of conference call with Prof. Cremonesi, folio 10116 dated 3.6.2005. Prof. Cremonesi is one of the most eminent physicians in the field of endovascular stents.

proposing a growing number of dedicated stents with a specific design. Increasingly, suppliers carry out the clinical trials to receive regulatory approval targeting a specific location (e.g. renal, femoral), even if the approval is subsequently received for endovascular procedures in general. Specialisation will certainly increase with the forecast growth in the number of procedures carried out in the endovascular area: a larger potential demand will allow companies to amortise the considerable investments necessary to develop a new stent and of obtaining regulatory approval for its use.

45. The trend towards specialised stents is clearest in the segment for renal (BX) stents, where suppliers already offer specialised products (e.g. Guidant's Herculink, Medtronic's Racer, Abbot's Jostent, Sorin's Radix) or plan to do so soon (J&J's Palmaz Blue Renal is expected to be launched in the next months[20]). Renal stents have a very low profile (to be able to access the renal arteries, which are smaller than it is the case for most other endovascular applications) and a strong radial force. A similar trend towards specialisation can be seen in the iliac-femoral area. Although it is not possible to exclude that some practitioners use non dedicated stents for renal or iliac-femoral procedures, there is a clear trend towards specialised use.

46. Therefore, while it is not yet possible to clearly delineate separate markets for stents entirely dedicated to specific endovascular procedures, there is a high degree of differentiation within the broad category of BX stents and of non-carotid SX stents. Switching between stents designed for specific procedures is not common, although it cannot be excluded outright. As a consequence, the competitive analysis of the endovascular stent markets will have to take into account the high degree of heterogeneity and the low degree of substitutability between types of stents.

47. To conclude on the markets for endovascular stents, the following separate markets have been delineated: the market for carotid stents, the market for non-carotid SX stents, the market for BX stents. The latter market in particular includes highly differentiated products as e.g. renal stents and iliac-femoral stents.

(b) The accessories

48. Endovascular guiding catheters, SGWs, PTA balloon catheters perform a similar function to the corresponding products in interventional cardiology.

49. Like for interventional cardiology accessories, each of these endovascular accessories is sold in different sizes and dimensions. However, according to the parties, a relevant market should be defined for each of these accessories, embedding different dimensions and shapes, 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. This conclusion was supported by the Commission's market inquiry.

50. Conversely, there is no supply side substitutability across accessories. Moreover, the Commission market inquiry indicated that endovascular guiding catheters, SGWs, PTA balloon catheters are in distinct markets from the coronary corresponding products (guiding catheters, SGWs, PTCA balloon catheters). Demand for the two lines of products is very different, as they are employed in large part by different physicians

[20] See Form CO p. 351.

carrying out very different procedures. Prices between the two lines of products tend to differ significantly.

51. From the supply side point of view, there is not a high degree of substitution between endovascular and cardiology devices. Although there are similarities between manufacturing technologies, endovascular devices tend to be larger in size, and can require different machinery. Furthermore, endovascular devices often have different designs and properties with respect to coronary devices in terms of e.g. profile and flexibility, which makes direct supply side substitution less likely. Finally, suppliers are not systematically present in both the interventional cardiology and endovascular areas.

52. Based on the above, the Commission concludes that a relevant product market should be defined for each of the following endovascular products: (i) guiding catheters, (ii) SGWs, (iii) PTA balloon catheters.

(c) Embolic Protection Devices

53. EPDs are small umbrella-type devices that are mounted on a catheter and placed beyond the lesion with the aim of trapping any material or debris dislodged during the angioplasty procedure. EPDs are used predominantly (but not exclusively) in carotid stenting procedures, where the risk of damage to the brain from loose material is highest.

54. Based on the specific characteristics of the product and its function of use, the Commission concludes that EDPs form a relevant product market.

3) Cardiac Surgery devices

55. Surgery of the heart is typically carried out to correct and repair multiple heart conditions, including coronary artery disease and congenital heart disease. There are three principal types of cardiac surgery: heart valve surgery, to replace heart valves; cardiac ablation, to treat serious cases of atrial fibrillation; and Coronary Artery Bypass Graft surgery ("CABG"), to treat coronary artery disease. With CABG, 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.

56. The parties submit that the following markets are affected in the cardiac surgery area: (i) beating-heart CABG products (stabilisation systems and accessories as blowers/misters); (ii) Endoscopic Vessel Harvesting ("EVH") devices. The products are described below.

(a) Beating-Heart Stabilisation Systems[21]

57. Beating-heart CABG stabilisation systems enable the perform CABG surgery on the heart while beating. A stabilisation system usually consists of a retractor, a stabiliser and a positioner. According to the parties, the three parts are usually sold together, but can also be purchased separately. The retractor is composed of a rack and two rails that are inserted into the chest after a sternotomy to keep the ribcage open and allow access to the heart. The stabiliser is a device that reduces cardiac motion in the target area through either suction or compression, thus enabling the surgeon to carry out the operation. The stabiliser is the most important component of the stabilisation system and accounts for approximately 75% of the total price. The positioner is a device used to manipulate the beating heart and to provide access to coronary arteries located at the back of the heart.

58. The Commission's market inquiry has broadly endorsed the parties claim that stabilisation systems should be treated as a single product. While some respondents affirm that it is more customary to purchase these products separately, this is not the proof that the components of stabilisation systems belong to different markets. Separate purchase is often due to the fact that there is not a one to one ratio in the purchase of the various components. Retractors are reusable devices, while stabilisers and positioners are disposable products. Furthermore, positioners are not needed for every procedure. Moreover, it is important to bear in mind that retractors are low value products that are sometimes given for free by the suppliers. More important, there is no interoperability between the components of different suppliers. This means that customers normally purchase all components from one supplier, even if in different quantities. The choice of the stabiliser is the main factor that determines the choice of supplier.

59. Based on these elements, the Commission concludes that a relevant product market should be defined for beating-heart stabilisation systems.

(b) Blowers/Misters

60. Blowers/misters are ancillary products that are used in conjunction with the stabilisation systems. Blowers/misters are low technology products used to clear blood away from and to deliver saline mist to the target vessel. The sales of blowers/misters are closely related to the sale of stabilisation systems.

61. Based on these elements, the Commission concludes that a relevant product market should be defined for blowers/misters.

(c) Endoscopic Vessel Harvesting Systems

62. EVH systems enable the surgeon to harvest the vein necessary for CABG procedure via a keyhole-sized incision in the leg or in the arm. It is a minimally invasive alternative to traditional vein harvesting that involves a long incision in the leg or arm to extract the portion of blood vessel that is needed for grafting. Endoscopic harvesting reduces both the pain and scarring, improves cosmesis and leads to shorter ambulation and recovery

[21] This market does not include beating-heart MIDCAB stabilisation systems. MIDCAB is a less invasive type of beating-heart surgery which involves a small incision in the chest. Beating-heart MIDCAB stabilisation systems, which do not constitute an affected market, are neither demand nor supply-side substitutes of beating-heart CABG stabilisation systems.

times and hence shorter hospital stays. Additionally, EVH leads to significantly lower infection rates.

63. The existence of a separate market for EVH systems has been confirmed by the Commission's market inquiry: although both endoscopic and traditional vessels harvesting deliver the same result (a portion of vessel used for CABG), they differ considerably in terms of procedure, required surgical skills, patient's recovery time and risk of complications. Furthermore, the price of EVH systems is considerably higher if compared to traditional vessels harvesting.

64. The Commission concludes that a relevant product market should be defined for EVH systems.

4) Cardiac Rhythm Management devices

65. Cardiac Rhythm Management devices are used for the treatment of severe heart rhythm disorders as arrhythmia (irregular heart beat), bradycardia (abnormally slow heartbeat) and tachycardia (abnormally fast heartbeat). Many devices are implanted in the patients' body and regulate the heart's rhythms through electrical stimuli.

66. The parties submit that there are no affected markets in cardiac rhythm management, as J&J is not active in the area. They consider however that three relevant product markets can be defined: (i) implantable pacemakers (devices that help regulate the heart's contraction patterns), (ii) implantable cardiac defibrillators (devices that prevent and control severe forms of tachycardia) and iii) cardiac resynchronisation systems (devices that treat the heart's inability to pump sufficient quantities of blood. They can also incorporate the functionality of a pacemaker or of a defibrillator). As there are no horizontal overlaps in the cardiac rhythm management area, the exact market definitions can be left open in this case. Table A below provides a comprehensive list of the affected product markets.

Table A

1) Interventional Cardiology (IC) devices
a) Coronary guiding catheters
b) Steerable GuideWires (SGW)
c) Percutaneous Transluminal Coronary Angioplasty (PTCA) balloon catheters
d) Bare Metal Stents (BMS):
e) Drug-Eluting Stents (DES)
2) Endovascular devices
a) Endovascular guiding catheters
b) SGW
c) Percutaneous Transluminal Angioplasty (PTA) balloon catheters
d) Balloon eXpandable (BX) stents
e) Self eXpandable carotid stents(SX)
f) Self eXpandable non-carotid stents(SX)
g) Embolic protection devices (EPD)
3) Cardiac surgery devices
a) Beating-heart surgery systems
b) Blowers and Misters
c) Endoscopic vessel harvesting (EVH) systems

B. RELEVANT GEOGRAPHIC MARKETS

67. All the products described above share the same characteristics for what regards their relevant geographic market. According to the parties, from a demand-side perspective, the relevant geographic markets may be national, as (i) reimbursement levels, and therefore prices, are generally determined on a national level; (ii) customers (hospitals, acting individually or in purchasing groups) and their procurement procedures are organised primarily on a national level. At the same time, the parties point out that, from a supply-side perspective, there are numerous factors suggesting EEA-wide geographic markets. For example, (i) the CE Mark is the only significant regulatory/legal barrier for products to be marketed in the EEA; (ii) production is centralised on a pan-European (often worldwide) basis and transport costs are low (less than 5% of sale value); and (iii) there are no significant "national" marketing/distribution barriers. The parties conclude that, even if the relevant geographic market is assumed to be national, industry characteristics establish the absence of any significant barriers to entry, expansion or repositioning across the EEA.

68. The Commission's market inquiry has clearly indicated that the relevant geographic markets are national, due to the following factors:

(a) Reimbursement schemes vary from country to country, in terms of products covered (not all EEA countries reimburse the cost of DES over BMS; when they are

reimbursed, price caps per device are often imposed) and reimbursement systems (e.g. reimbursement based on costs incurred, prospective reimbursement based on the type of condition treated, allocation of a global budget to the hospital);

(b) Procurement processes differ widely between countries. In some countries (e.g. Germany) group purchasing organisations act on behalf of a group of hospitals and process and select offers from major suppliers; in other countries (e.g. Italy and France) public tenders are widely utilised; in yet other countries (e.g. the U.K.) procurement is managed mostly by hospital trusts with 'informal' tenders.

(c) Partly on account of the variation in reimbursement and procurement systems, prices present very significant variations between countries. For example, according to the parties the average selling price of a J&J BMS in 2003 was € […]* in Germany, € […]* in Spain, € […]* in Italy and € […]* in The Netherlands. Similar variations can be found across the product range of J&J, Guidant, and their competitors;

(d) Differences in prices notwithstanding, virtually no customer has affirmed to source the products from abroad. While some customers are not aware of the existence of such differences, many have reported that sourcing from abroad is too risky in terms of inventory management and regular updates on products. Other customers have reported that suppliers actively discourage alternative forms of sourcing;

(e) Related to the point above, most customers have indicated that a local sales office is a necessary condition for a supplier to be able to penetrate a market. The role of local sales personnel ranges from informing the physicians of new products offers and new clinical data on such products, to preparing offers and bids for formal and informal tendering processes, to ensuring speedy delivery of the devices to hospitals;

(f) Finally, the parties' and competitors' market shares, at least as regards some of the products affected by the transaction, vary significantly across the different Member States.

69. In view of these elements and coherently with previous decisions in medical devices cases[22], the Commission concludes that the relevant geographic markets for the products described in the section of relevant product markets are national.

VI. COMPETITIVE ASSESSMENT

A. INTERVENTIONAL CARDIOLOGY

1) Drug-eluting stents

(a) Introduction

70. As background, it seems appropriate to briefly mention the main investigative actions that the Commission has undertaken. Besides the parties' extensive submissions, a thorough market investigation has been conducted with a view to collecting the opinions

22 See, for example, Commission Decision 2004/322/EC of 2 September 2003 in Case No COMP/M.3083 GE/Instrumentarium (OJ L 109, 16.4.2004, p. 1); Case No COMP/M.3146 Smith & Nephew/Centerpulse; and Case No IV/M.1286 Johnson&Johnson/DePuy.

of the main stakeholders. In particular, the Commission has addressed a number of information requests to all of the parties' competitors and to a large number of hospitals (the customers) across Europe. Most of the parties' major competitors have had the opportunity to make their views known in meetings with the Commission. A number of competitors have acted as active complainants. In order to refine the investigation on the ongoing DES programmes, the Commission has interviewed a small number of eminent physicians who are involved at the highest level in clinical trials of DES (here below "the experts"). Such experts have been selected from a list of names provided by the parties as well as the competitors acting as complainants. Their input is crucial for the purpose of the outcome of the market investigation and their opinion is highly valued. Significant weight has also been given to the large number of studies prepared by specialised consultants[23] as well as to the periodic reports published by the major financial analysts. Finally, the Commission has handled the problem of IP rights raised by some complainants in cooperation with the US FTC.

(b) The parties activities

71. J&J, through its subsidiary Cordis, sells a range of interventional cardiology devices for coronary diagnosis and intervention, including diagnostic catheters, diagnostic guidewires, catheter sheath introducers, guiding catheters, steerable guidewires, PTCA balloon catheters, coronary stents (BMS and DES), embolic protection devices and accessories. In 2003, J&J Cardiology had sales in the EEA of € […]* million. DES sales accounted for […]*, BMS for […]*, diagnostic devices for […]*, PTCA balloon catheters for […]*, guiding catheters for […]*, catheter sheath introducers for […]* and steerable guidewires for […]* of J&J' total sales in EEA. Other accessories accounted for less than […]* each.

72. Guidant sells its interventional cardiology products via its Vascular Intervention division. Guidant's range of interventional cardiology products includes guiding catheters, steerable guidewires, PTCA balloon catheters, coronary stents (BMS), atherectomy devices and accessories. Guidant's sales in 2003 in the EEA were € […]* million: BMS accounted for […]*, steerable guidewires for […]*, PTCA balloon catheters for […]*, guiding catheters for […]* and others for […]*.

(c) The features of the market

73. Interventional cardiology is a relatively recent, innovation driven business which has registered dramatic growth over the last few years. In 1987, the first coronary stent was implanted in a human being. In the late 1980s and early 1990s a large number of new interventional devices were invented and perfected and, by 2000, each year about two million angioplasties were performed worldwide. The use of stents had by then also become commonplace. The first drug-eluting stent was put on the market in Europe in 2002. The overall interventional cardiovascular market is expected to grow significantly over the next five to ten years, fuelled by new and improved therapies and products, proven clinical performance in new indications, increased reimbursement and the overall ageing of the population. Interventional cardiology has experienced a CAGR (compound annual growth rate) of 11% over the last five years. Worldwide cumulative

23 See Biba 2004, Millennium 2003, Frost & Sullivan, 2004, Morgan Stanley, "*The 2005 Investors' Guide to Interventional Cardiology*", 2005.

growth is expected to be at about 15% on average per year, at least for the next three years and at about 13% over the next ten years. In value, the market is expected to grow from approximately $ 5.5 billion this year to $ 11.5 billion in 2013 (CAGR of 8%)[24].

74. As regards in particular DES, overall growth in this market is becoming more moderate, given that DES penetration begins to reach peak levels[25]. However, in Europe, the uptake of DES has not been as explosive as in the US due to the price sensitive nature of the European market. Penetration in 2004 was estimated at around 56%, up from 32% in 2003. The total value of the market was around € 1.1 billion in 2004. As a consequence, future growth in DES in Europe will depend essentially on the switching from BMS to DES.

75. Rapid, ongoing technological innovation and product development are key drivers of competition. As a consequence, market leadership may fluctuate over time, at least in some interventional cardiology devices. Recent history in coronary stents shows that each breakthrough has changed the competitive landscape, like for instance the introduction of DES. However, to date the market for coronary stents seems to be in a somewhat different, more mature phase[26], in the sense that there are no short term expectations of revolutionary breakthrough; rather, the general sentiment is that over the next three years there will be improvements at the margin of the current products.

76. The interventional cardiology devices are differentiated products, where quality of performance and innovation are key parameters. This feature is perhaps less accentuated for some of the accessories.

77. The interventional cardiology field is characterised by significant barriers to entry. Firstly, it is a highly innovative area with rapidly evolving products, which requires important investments in R&D. As an approximate measure, the major medical devices suppliers tend to dedicate 10-15% or their revenues to R&D; R&D spending can be considerably higher for particularly innovative projects, such as DES (see below for details).

78. Secondly, the major medical devices suppliers hold numerous patents on the essential features of these products. A new entrant, especially if targeting the US market, would have to face litigation risk or enter into licensing agreements with existing suppliers[27].

79. Thirdly, the launch of a new innovative product entails very long and costly clinical trials to demonstrate their safety and efficacy. As discussed in the section on market definitions above, DES need approval both as Class III medical devices and as drug carrying devices. Moreover, the major vascular devices suppliers tend to conduct clinical trials on a larger number of patients, in order to obtain more robust results on the efficacy of their products. In the same vein, there is an increasing tendency to carry out

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24 See […]*; forecasts by financial analysts (see, inter alia, Morgan Stanley, Biba, Millennium, cited above) do not differ significantly.

25 See Morgan Stanley, *The 2005 Investors' Guide to Interventional Cardiology*", 2005, p. 7.

26 See Morgan Stanley, ibidem.

27 See replies to questions 50 to 52 of Questionnaire to competitors interventional cardiology I phase, dated 16 March 2005; see also Medtronic submission folio 9509 dated 30.5.2005, White paper.

additional comparative trials between devices of different brands[28]. Another nascent practice, which is already occurring in the neighbouring market of endovascular devices, and is likely to develop in coronary stents[29], is to conduct ad hoc clinical studies dedicated to specific lesions or categories of sensitive patients (e.g. the diabetics), in order to obtain more "tailor made" pertinent clinical data[30]. All these features further increase the hurdles a new entrant or a fringe incumbent player has to overcome in order to become established in the market place.

80. Fourthly, established suppliers are very well known by the customers and have dedicated and technically prepared sales forces. Additionally, they have close relationships with key opinion leaders in the medical profession, sponsoring research and carrying out their clinical trials at the most prestigious medical institutions[31].

81. Finally, all major suppliers offer a wide range of products in interventional cardiology, thus to match the range offered would require significant additional investments by a new entrant[32].

82. Clearly, entry in interventional cardiology is not impossible, especially if the new entrant does not have the ambition to become a global player with a significant market share. However, every entrant would have to deal with these potential hurdles: R&D financing; securing property rights for product development (or accepting a high litigation risk); long time-to-market for new products; organisation of effective sales force and hospital presence; and building up an acceptable range of products.

83. The demand is constituted by hospitals or hospital groups, national healthcare procurement organisations or joint procurement entities. They generally resort to tendering procedures for the procurement of supplies, although informal negotiations and package deals are also a recurring feature of the market. The scope of the tender is typically limited to specific cardiovascular products or covers a range of cardiovascular products.

84. Hospitals typically multi-source in order to avoid dependence on one supplier and obtain for each specific product the supplier which offers the best price/quality combination and specific needs. Joint purchasing is an increasing phenomenon across the EEA, although it is difficult to quantify.

85. Hospital administrations procure these devices relying on the input of physicians (cardiologists, radiologists, vascular surgeons, cardiac surgeons), who use the devices in the therapies that they provide. Hospitals/physicians base their purchasing decisions on a

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28 See below the studies *Reality* and *Sirtax* comparing the efficacy of J&J Cypher to BSX Taxus.

29 See Sorin, reply to question n. 8 of Questionnaire to competitors interventional cardiology I phase, folio 81830, dated 4 May 2005.

30 […]*

31 See Sorin, reply to Questionnaire to competitors interventional cardiology I phase, folio 81830, dated 4 May 2005, Medtronic, White paper.

32 See replies to questions n. 34-37, 41 and 63-65 of Questionnaire to competitors interventional cardiology I phase, dated 16 March 2005; in particular, see Sorin, Biotronik and Medtronic. See also replies to questions 13-14 of Questionnaire to competitors interventional cardiology II phase, dated 4 May 2005.

variety of factors such as (i) product quality/performance; (ii) price ; (iii) image/reputation; (iv) services/customer support. Not surprisingly, hospital administrations tend to focus more on price than physicians; physicians tend to be quality-oriented and concerned with product performance. The relative weight of the various factors mentioned above is likely to change over the lifecycle of a product. For newer therapies and technologies non-price factors may have a greater weight, while for more mature therapies and technologies the relative weight of price may become more important in the procurement decision, as long as an equally good level of performance is secured.

86. A trend across segments is that hospitals are increasingly seeking to exploit their buying power as they operate under growing budgetary pressure. Healthcare reforms across Europe, dictated by government policies to contain growing healthcare costs, provide incentives for hospitals to approach procurement more efficiently. As a result, cost considerations are a far greater procurement driver than they were some years ago. That said, the importance of this trend remains pretty uneven across European countries.

87. As to the reimbursement rules applicable to interventional cardiology operations, there are mainly two practices across the countries of the EU, namely a fee for service and a flat rate based on Diagnostic Related Groups. In both cases, as a matter of fact reimbursement rules impact on hospitals purchasing decisions and greatly limit the latter's budget freedom. This is certainly a constraint which has generated two effects: it has significantly slowed and delayed DES uptake in the market, DES prices have been on average lower than in the US.

(d) The competitive landscape

88. As to the competitive landscape, the market is characterised by the presence of several competitors with different size and ambitions. The investigation has shown that in the area of interventional cardiology there are two leagues of players. In the top tier, to which the parties belong, there are large global companies competing on a worldwide level, that can count on the following:

i. Top quality devices, primarily the stents, supported by good and abundant clinical data.

ii. Strong relationships with customers and good reputation earned through the provision of good products, customer service, educational programs, support by prestigious medical institutions and key opinion leaders.

iii. Vast financial capabilities to finance massive R&D programmes: as stated already, R&D spending by the major suppliers is in the range of 10-15% of revenues but can be considerably higher for projects such as DES. As an example, top tier players are spending massive sums ranging from one to several hundred million US dollars[33]. For the same programmes the second tier players have allocated much smaller sums[34].

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33 See […]* replies to question n. 53 of Questionnaire to competitors Interventional cardiology Phase I, summarised in note to the file, folio n. 16063, dated 16 June 2005.

34 See replies to question n. 53 of Questionnaire to competitors Interventional cardiology, Phase I, summarised in note to the file, folio n. 16063, dated 16 June 2005.

iv. Wide geographic reach -- that is, a strong and widespread presence in the three most lucrative markets, the US, Japan and Europe; the US, in particular, being the largest (60% of worldwide revenues) and most profitable market, is strategic in order to amortise massive R&D investments and reach economies of scale. As regards more specifically Europe, a capillary presence across the countries of the EU is necessary and yet costly as it requires ad hoc investments in terms of local sales forces, inventory, marketing, after sales and training.

v. A strong patent portfolio: as it will be further explained later, patent protection is crucial in order to gain access to the US market and to a lesser extent to Europe. However, for a firm with the ambition to be a global player, a presence in the US is strategic as the latter market is by far the largest and the most profitable in the world for vascular devices in general and for stents in particular[35]. As a consequence, the ability to properly compete in the US market increases global revenues and profits significantly and thus the attractiveness of R&D projects. This is more so for large, US based, medical devices suppliers, who have to select projects among a large pool of very attractive investment opportunities (e.g. in neurology, orthopaedics, etc.).

vi. Broad product range, i.e. a strong presence in the key market for coronary stents (previously the BMS and to date the DES) to be combined with a diversified range of accessories, namely steerable guidewires, balloon catheters and guiding catheters. While these accessories are low-margin and more commoditised products, they are nonetheless strategic to the extent that they facilitate package deals, a practice which is very widespread in the US[36] and not insignificant in Europe. Based on the information collected in the market investigation, it appears that package deals, generally in the form of combination between the stents and one or more accessories, count on average for about 30% of the totals sales in Europe[37]. Secondly, especially in Europe, where markets have a national geographic scope and some of them are tiny, diversification across IC neighbouring markets enables companies to reach critical mass on a country basis more easily and amortise costs relating to local distribution and sales (in 2004 the market for accessories in Europe amounted to around Euro 310 million, i.e. little less than 30% of the total value of the market for interventional cardiology devices).

89. To date, the only firms which can rely upon the above assets are J&J, Guidant, Medtronic and Boston Scientific. Abbott, a big pharmaceutical company, has entered the market with the ambition to become a key player in vascular devices. While it is still

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35 The US coronary stent market was worth around $ 3 billion in 2004, and is forecast to reach $ 3.6 billion in 2008, that is 60% and 62% respectively of worldwide sales. The European coronary stent market is the second largest, but generates considerably lower sales: according to the parties, the EEA market was worth around € 800 million in 2004. The Japanese market is the third largest, accounting for around 10% of worldwide sales. Furthermore, profit margins are considerably higher in the USA than in Europe: although the cost base is roughly the same, average selling prices are significantly higher in the USA (the price of a DES in 2004 has been estimated at $ 1,744 in Europe and $ 2,525, or 45% more, in the USA). Although prices will fall on both sides of the Atlantic, the price gap is estimated to increase to 68% in 2008. See Morgan Stanley, "*The 2005 Investors' Guide to Interventional Cardiology*", 2005, p. 19-23.

36 See Frost & Sullivan, Millennium, Morgan Stanley, "*The 2005 Investors' Guide to Interventional Cardiology*".

37 See replies to question n. 5 of Questionnaire to competitors Interventional cardiology, Phase II summarised in note to the file folio n. 16062, dated 16 June 2005.

uncertain whether Abbott can succeed given that at the moment it lacks in this area a solid track record and customer base, it is undoubtedly the most serious candidate to join over time the top tier of IC players. In fact, as it will be explained later in the text, at least two of these firms, Medtronic and Abbott, have a weak position in the US market precisely due to their lack of access to some key patented technology.

90. In the second tier there are "Local players", such as Sorin, Biotronik (who will distribute in Europe Conor's DES stent) and others. As it will be further explained later, these suppliers are focused only in some regions of the Continent, have a much smaller size, less diversified product range, small budget for R&D. While these companies can, on occasion, exert some competitive constraints, especially if they manage to develop successful products in the key market for DES, overall, they remain fringe players as they lack the above mentioned assets to worry the market leaders.

(e) Impact of the merger in DES

91. As stated above, stents are currently the most important area of development in interventional cardiology. A recent breakthrough has seen the development of the drug-eluting stents ("DES"), which were first marketed in Europe by J&J in 2002. DES are rapidly replacing traditional, 'bare metal' stents ("BMS") in a large number of operations, despite being approximately three times as expensive, and are at the same time expanding the number of Coronary Artery Disease pathologies that can be treated with interventional cardiology. As stated already, DES are meant to prevent restenosis or at least to maintain restenosis within rates in the 8%-10% range, significantly lower that the 20%-25% rates for bare metal stents.

92. For the purpose of regulatory approval and commercialisation DES undergo thorough clinical trials designed to check DES safety and efficacy[38]. A first clinical trial is

[38] Regulatory studies are performed to obtain (pre-) marketing approval (e.g. in the context of the CE Marking process in the EU or the IDE/PMA process required by the FDA in the USA). The clinical testing of experimental drugs is normally done in three phases, each successive phase involving a larger number of people. Once the FDA has granted a New Drug Approval (NDA), pharmaceutical companies also conduct post marketing or *late phase three/phase four studies*. **A Phase One Study:** Phase I studies are primarily concerned with assessing the drug's feasibility/safety (first-time use in man). This initial phase of testing in humans is done in a small number of healthy volunteers (20 to 100), who are usually paid for participating in the study. The study is designed to determine what happens to the drug in the human body-how it is absorbed, metabolized, and excreted. A phase I study will investigate side effects that occur as dosage levels are increased. This initial phase of testing typically takes several months. About 70 percent of experimental drugs pass this initial phase of testing. **A Phase Two Study:** Once a drug has been shown to be safe, it must be tested for efficacy. This second phase of testing may last from several months to two years, and involve up to several hundred patients. Most phase II studies are randomized trials. One group of patients will receive the experimental drug, while a second "control" group will receive a standard treatment or placebo. Often these studies are "blinded"-neither the patients nor the researchers know who is getting the experimental drug. In this manner, the study can provide the pharmaceutical company and the FDA comparative information about the relative safety of the new drug, and its effectiveness. Only about one-third of experimental drugs successfully complete both phase I and phase II studies. **A Phase Three Study:** In a phase III study, a drug is tested in several hundred to several thousand patients. This large-scale testing provides the pharmaceutical company and the FDA with a more thorough understanding of the drug's effectiveness, benefits, and the range of possible adverse reactions. Most phase III studies are randomized and blinded trials. Phase III studies typically last several years. Seventy to 90 percent of drugs that enter phase III studies successfully complete this phase of testing. Once a phase III study is successfully completed, a pharmaceutical company can request FDA approval for marketing the drug. **Post-Marketing - Late Phase Three/Phase Four Studies**. In late phase III/phase IV studies, pharmaceutical companies have several objectives: (1) studies often compare a drug with other drugs already in the market; (2) studies are

generally conducted on a small number of patients with a view to establishing safety. A second trial on a larger sample of patients is then meant to prove safety and efficacy and is often used as clinical evidence to obtain EC approval for commercialisation. A third trial only required by the US FDA is meant to prove the comparative efficacy of a stent relative to other products already on the market. The performance of a stent under trial is established on the basis of periodic measurements of the various dimensions of the vessels under treatment (angiographic data). For instance, one of the most relevant angiographic data is the late lumen loss (LL), that is the difference between the vessel diameter immediately after the stenting procedure, and at a follow-up check sometime later (six months or more). Although there are no unanimous views on this point, many physicians believe that a significant late lumen loss should be associated with the restenosis. Also regulatory agencies such as the FDA utilise LL as a key parameter in order to assess the efficacy of a DES under trial, and decide upon regulatory approval for commercialisation. DES safety is also established by reference to so called "clinical event data", that is the various adverse events that the patients under treatment can experience. Such events range from the target vessel revascularisation (the need to repeat the stenting due to a new blockage) to death and are otherwise known under the acronym MACE (major adverse cardiac events)[39].

93. DES are increasingly taking the lion's share of the interventional cardiology market (the parties forecast that in 2008 they will account for around […]* of the € […]* total European sales). Conversely, the markets for BMS and other accessory devices (balloons, catheters, wires) will experience falling unit prices and, for BMS and balloons, a significant contraction in the absolute size of the market.

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often designed to monitor a drug's long-term effectiveness and impact on a patient's quality of life; and (3) many studies are designed to determine the cost-effectiveness of a drug therapy relative to other traditional and new therapies. Clinical studies are conducted according to the principles/guidelines of Good Clinical Practices (Global requirement) and follow International Harmonised Standards ISO.

[39] **Clinical event data** are usually reported as the percentage of patients who experienced that particular event. There are many parameters in order to evaluate the clinical endpoints. One of the important clinical endpoint is **TVF (target vessel failure)** which includes death and either target vessel or target lesion failure. This is the primary endpoint that FDA requires for approval. **TLR (target lesion revascularization)** and **TVR (target vessel revascularization)** refer to a repeat intervention (as decided by the clinician) due to a blockage within the stented region and in the stented vessel. **MI (myocardial infarction)** refers to a heart attack. **MACE (major adverse cardiac events**) is collective measurement that typically encompasses death, TLR, TVR, and MI.

Angiographic Data are measurements of various dimensions and parameters of blood vessels, and are usually reported as an average measurement or percentage for the group of patients. Among them there are: **Binary restenosis** which is the percentage of patients whose vessel diameter had been reduced by 50% or greater at the time of angiographic follow-up. **RVD (reference vessel diameter)** is the average diameter of the inside of the blood vessel along the length of the stent immediately after stent implantation (i.e., post-procedure). **MLD (minimum lumen diameter)** is the minimum diameter of the lumen (the inside of the blood vessel) along the length of the stent. **% DS (percent diameter stenosis)** is the average percentage of the RVD that has been "lost" as a result of restenosis. **Late lumen loss,** or simply (LL). It is amount (in mm) of the RVD that has been "lost" as a result of restenosis. **Aneurysm formation** is a widening of a blood vessel. This could result in lost function and could pose the threat of rupturing.

IVUS Data can be used to make measurements or to detect abnormalities. The main parameters are: **Neointimal hyperplasia volume** is the volume of the neointimal layer of cells that results from cells proliferation following balloon injury. **Incomplete stent apposition** refers to a situation in which one or more stent struts are not completely apposed to the vessel wall. **Stent thrombosis** refers to blood clots forming on the stent surface, which could eventually break off and lead to MI or stroke. Stent thrombosis is usually reported as acute (within 24 hours of the procedure), sub-acute (within 30 days), or late (>30 days).

94. In the market for DES, as stated earlier, 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. The latter is taking the lead in the market, reaching a share in the EEA of around [50 – 60%]* in 2004, while J&J is around [40 - 50%]*. These market shares by and large reflect the situation at national level, although some differences are recorded, with J&J taking the lead over Boston in some countries of the EU.

95. The parties argue that the merger will not give rise to adverse effects on competition in the market for DES for a number of reasons. Firstly, the market for DES is very competitive and innovation driven, with Boston scientific taking the lead over J&J. Secondly, the demand for DES continues to grow rapidly at the expense of BMS. These developments make the DES business extremely attractive to potential entrants. A number of competitors are about to launch or are expected to launch in the next year or so their DES in the European market, such as Medtronic, Abbott, Sorin, Conor/Biotronik, Terumo and others. Guidant is only one among a number of potential entrants in this market, […]*.

96. The market investigation has provided the following picture.

(1) Boston Scientific

97. In its market investigation the Commission has first carefully scrutinised the current position of the two incumbent players in the DES market. In this respect, the investigation has revealed that, while it is an undisputed fact that Boston Scientific has taken the lead of the DES market, the current market situation may not adequately reflect J&J's real strength in DES due to the following reasons.

98. To begin with, since the launch of J&J's Cypher until allegedly lately, J&J has been confronted with some manufacturing constraints. According to the market investigation, one of the main reasons was that the US FDA, at a late stage of its approval process, imposed a very short shelf life (because of the drug coating, the DES has a limited period of validity) on Cypher (only three months as opposed to six months initially planned), as a result of which J&J could not sufficiently scale-up its production to replenish its inventory[40]. Reportedly, the above problem has essentially involved the US market. However, one respondent to the market investigation contends that the issues of capacity constraints has also involved Europe since European capacity has partially been diverted to satisfy American demand, thus creating a shortage of supply in the EU[41]; something which appears commercially reasonable given that US sales generate in principle the highest margins. Other respondents to the Commission market inquiry also refer to unspecified delays that J&J had from time to time encountered in the timely delivery of its DES to hospitals in Europe.

99. In a reply to the Commission's specific question on this point, J&J acknowledges it has faced difficulties in meeting demand in the US, although due to different reasons: […]*. Against this background, it cannot be ruled out that J&J current position in the DES market may, at least in part, be limited by its capacity constraints.

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40 See Morgan Stanley, "*The 2005 Investors' Guide to Interventional Cardiology*", 2005, p. 23.

41 […]*

100. The investigation has also revealed additional factors indicating that Boston Scientific's market leadership may soon be challenged. The latest clinical trials seem to indicate that […]*[42][…]*[43][…]* [44] […]*[45][…]* [46] […]*.

101. Most of the experts interviewed by the Commission voice only moderate concerns about the outcome of the above cited trials, and treat these results with caution, pointing to the fact that these trials do not provide hard clinical evidence from which to draw a conclusive judgement. In fact, most of them, although expressing on balance a slight preference over Cypher, consider Taxus' performance by and large comparable to Cypher[47]. The comments from financial analysts on this issue are mixed. Some of them signal that, based on the data resulting from the above cited studies, J&J's DES Cypher is proving to be slightly more effective and perhaps a bit safer than Boston Scientific's Taxus[48]. Based on the above some financial analysts have revised their market share projections in DES slightly in favour of J&J. Other analysts are instead more agnostic about the possible negative implications of the outcome of the cited trials over Boston Scientific sales.

102. About the significance of the cited trials, the parties retort that these trials failed to prove Cypher's superiority in terms of either of the primary clinical endpoints. Therefore, according to the parties, the overwhelming current view in the analyst and medical community is that these trials have not established J&J's superiority, and thus any shift in market shares favourable to J&J will be very modest. The parties have also provided sales of the last few months to show that no significant shift has taken place.

103. Taking all the above evidence into account, it can be concluded that due to the factors cited above, Boston Scientific's leadership in the DES is likely to be more robustly challenged in the short/mid run, primarily by J&J, as well as by other new entrants. However, based on the evidence in the file, it cannot be assumed this will turn Boston Scientific into an ineffective competitive constraint. The negative implications that Boston Scientific may bear on its DES sales as a result of the above factors seem, for the time being, relatively modest.

(2) Guidant

104. Turning to Guidant, based on the information collected in the market investigation, it appears that, absent the merger, Guidant would have been one of the new entrants in

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[42] […]*

[43] […]*

[44] […]*

[45] […]*

[46] […]*

[47] See replies to question n. 3 of questionnaire to *Experts*.

[48] See Morgan Stanley, "*The 2005 Investors' Guide to Interventional Cardiology*", 2005, p. 47-48. See also Lehman Brothers, 7/03/2005, Industry update on medical supplies and devices, p. 2 and JP Morgan, 7/03/2005, Cardiovascular devices, pp. 2-3, 9-10, in Guidant's submission on Medtronic, folio 5734, dated 23 March 2005.

DES with the best prospect of success, that is to say a supplier likely to enter the market of DES and gain a significant market share in two/three years time. For instance, at the end of 2004 and beginning 2005, specialised financial analysts forecasted Guidant would have become one of the market leaders in DES in the years 2007-2008, with shares around 25-35% in the worldwide market[49].

105. More specifically, the view of the market is that Guidant's strong prospect of success in DES was based on the following assets:

i. Guidant has one of the best stent platforms. The existing Guidant's state of the art cobalt chromium BMS platform will be the platform for its DES stent. This platform combines excellent characteristics: it is very deliverable, very flexible, and very visible thanks to the good radiopacity of the cobalt chromium alloy. It is a platform already well established on the market and very successful which has enabled Guidant to maintain market leadership in BMS. About the excellence of Guidant stent platform the evidence in the file is cogent. The replies from customers and competitors to the Commission market inquiry unanimously acknowledge this point[50].

ii. Guidant has a good drug for the treatment of coronary vessel lesions, Everolimus. […]*. Everolimus belongs to the same family of drugs as J&J's Sirolimus, i.e. the Limus family that includes Rapamycin (an antibiotic that exists in nature) and Rapamicyn analogues. These drugs have immunodepressant properties; Sirolimus is employed to prevent rejection in organ, in particular kidney, transplantation. The drugs interact with T cells and blunts their ability to release the chemicals that cause inflammation, which in turn leads to restenosis. The mechanism of action of Everolimus, as well as its antiproliferative and anti-inflammatory effects are very similar to J&J Sirolimus[51]. Besides Everolimus, there are also few other Rapamycin analogues similar in chemical structure and mechanism of action to Sirolimus. Biolimus A9 is being developed by Biosensors. ABT-578 is being developed by Abbott and has also been licensed to Medtronic. The only other drug which has proved successful in the treatment of restenosis is Paclitaxel (Taxol), used by Boston Scientific and Conor Medsystems. Paclitaxel is a cancer drug which binds to proteins within the cell and stops cell division without addressing inflammation; paclitaxel has also a very narrow therapeutic window whereas rapamycin has a broad therapeutic window[52].

iii. As to the efficacy of everolimus in the treatment of restenosis, some of the competitors have claimed that Guidant drug is among the most tested and promising drugs available on the market. This drug has had very positive results in all the

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49 See Morgan Stanley, "*The 2005 Investors' Guide to Interventional Cardiology*", 2005 and other analysts reports cited infra; see also Guidant internal projections dated Nov. 2004 (annexe 41 to Form CO, doc. 1), which forecast its worldwide market share at around 40% in 2007-2008.

50 See replies to questions n. 59-60-61 of Questionnaire to competitors, Interventional cardiology, I phase, dated 16 March 2005; see replies to questions n. 49 of Questionnaire to customers, Interventional cardiology, I phase, dated 16 March 2005. See analysts reports, cited above.

51 See […]* Conor, minutes of the meeting with the Commission, folio 10381, dated 7 June 2005; Abbott, submission to the Commission, folio 10526, dated 08/06/2005 (Conf.); see also replies to questions n. 3 and 18 in Questionnaire to *experts* dated 4 May 2005.

52 See Abbott and Conor, ibidem.

various trials conducted by Guidant using different polymers and stents, i.e. the first trial on Vision (Guidant's ongoing DES programme, which is developing a cobalt chromium stent with a durable polymer), as well as the two trials conducted by Guidant on its Champion DES (the Champion DES, which featured a bioabsorbable polymer on a stainless steel stent, was abandoned by Guidant at the end of 2004)[53]. The parties retort that Everolimus has been tested only in small trials with a very limited number of patients (overall, less than 100). The other drugs, primarily Paclitaxel (the drug used by Boston and Conor), Sirolimus (J&J drug), but also ABT-578 (the drug tested by Abbott and Medtronic) have undergone much more extensive trials.

iv. The investigation has revealed that there are not yet compelling clinical data showing Everolimus' efficacy. The parties legitimately point to the small sample of patients having been treated with Everolimus. Moreover, two of Guidant's trials involved a drug/stent/polymer combination different from the one Guidant is currently running. As a consequence, the probative value of these data is less relevant in predicting Everolimus' success. Nonetheless, the predominant view in the business and scientific community[54] is that Everolimus is a very effective drug to treat restenosis, and is very close to Sirolimus in terms of therapeutic effects and mechanism of action.

v. The outcomes of Guidant's first clinical trials on its ongoing DES Vision programme are promising. In essence, the data generated from the first Guidant *Spirit* trial on Vision which were released towards the end of September 2004 looked solid, comparable to Cypher and stronger than Taxus[55]. All the experts interviewed have unanimously confirmed the above, expressing very positive judgements regarding Guidant's DES[56]. The comments by virtually all financial analysts at the time of the release of the data and for all over the time immediately preceding the announcement of the merger with J&J, with very few exceptions, were also very positive[57]. Most of the analysts even predicted that with the Vision programme on track and the Champion programme definitively cancelled[58], Guidant

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53 See Medtronic submission on Guidant presentation of the clinical trials for Guidant's DES, folio n. 10560, dated 8 June 2005, and Medtronic submission on analysts reports commenting Guidant's DES trials in the period September 2004-January 2005, folio 10429, dated 8 June 2005; replies to questions n. 9-10-11 of Questionnaire to *experts,* dated 4 may 2005.

54 See replies to questions n. 3 and 18 in Questionnaire to *experts* dated 4 May 2005; see also replies of Conor, Medtronic, Sorin, cited supra.

55 Spirit First is a first in man 60-patient, prospective, randomized, single blind trial evaluating Guidant's Spirit stent with an uncoated vision stent in previously untreated lesions. Overall, the patients enrolled in the trial had fairly easy lesions to treat. This type of patient who was enrolled in this trial was similar to other early DES trials, which include Taxus II, Ravel (J&J's Cypher) and Endeavor. The 6-month angiographic data looked extremely positive. The primary endpoint of 6-month angiographic in-stent late loss was 0.10 mm for the DES arm compared to the in-stent late loss results for Endeavor (0.60mm), Cypher at 8-months (0.17 mm) and Taxus II at 9-months (0.39mm). As for in-segment late loss, the treated arm registered late loss in the 0.09 mm range, vs. 0.60 mm in the control arm. The results were considered very good and they compare very well with competitive programs.

56 See replies to questions n. 9-10-11 of Questionnaire to *experts* dated 4 May 2005.

57 See Medtronic submission on analysts reports commenting Guidant's DES trials in the period September 2004-January 2005, folio 10429, dated 8 June 2005: Morgan Stanley, Merrill Lynch, Citygroup, Lehman Brothers, JP Morgan, Credit Suisse, Bern Stearn, Goldman Sachs.

58 […]*.

was strong candidate to become market leader in two years time from the launch (2007-2008, with a launch in the first quarter of 2006), with market shares projections up to 30% and more[59].

106. That said, there is also evidence in the file that some reservations existed vis-à-vis the prospect of success of Guidant's DES programme due to the following reasons: i) the early stage of Guidant's clinical trial program, as a consequence of which a certain degree of uncertainty over the final outcome of the programme would persist; ii) the repeated failures of Guidant in its previous DES programmes, which have translated into a substantial delay to enter the DES market.

107. On the first point, as a matter of fact, most experts have indeed pointed to the early stage of Guidant trial and the small sample of patients being treated[60]. The financial analysts, instead, with few exceptions, expressed rather enthusiastic comments at the time and after the release of Guidant's first trial, predicting a successful entry for Guidant in early 2006[61].

108. As regards the state of development of Guidant ongoing DES programme, the parties point also to the fact that Guidant's trials are based only on primary angiographic endpoints, in particular the late lumen loss, and not on clinical primary endpoints, such as target vessel revascularization. And while these angiographic results from the trials may look promising, they have only limited value as surrogates for hard clinical endpoints. This is so because clinical endpoints provide direct evidence of how successful the DES is in treating the clinical condition (restenosis) and avoiding clinical events (e.g. repeat treatment), while angiographic endpoints rely on indirect evidence (e.g. late lumen loss measures the difference of the diameter of the vessel immediately after the stent placement and at a follow-up check some time later). To support their claims, the parties refer to the positions taken by leading physicians in this field, explaining that even very promising angiographic results need to be confirmed in trials having as primary endpoints clinical parameters. Reference is also made to the US FDA traditional practice to use clinical endpoints in large pivotal trials to overcome the limited evidence provided by angiographic surrogate measures.

109. As to the fact that Guidant might have further significantly delayed its entry into DES, the evidence points to the contrary. It should be borne in mind that, after the very positive results of the first trial were released and prior to the announcement of the merger with J&J around October 2004, Guidant had reviewed its timeline, readjusted its previous forecast (based on the timeline of the previous Champion programme) and thus planned its entry in the EU in early 2006. […]*. The date of early 2006 has also been publicly indicated by Guidant management to the financial community as the timing of the DES launch in Europe. Moreover, after the release of Guidant first clinical trials on Vision, most analysts indeed forecasted and believed in Guidant entering the EU market in early 2006[62]; only a few of them forecast Guidant's entry in second quarter 2006, just as few others were more optimistic and forecast an early entry in end 2005. Still as late

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59 See in particular Morgan Stanley, Lehman Brothers, cited supra in note n. 53.

60 See replies from Dr. Chevalier, Morice, El Khouri, to questions n. 9 of Questionnaire to *experts* dated 4 May 2005.

61 See Morgan Stanley, "*The 2005 Investors' Guide to Interventional Cardiology*", 2005, p. 40.

62 See analysts reports, cited supra.

as January and February 2005, some analysts maintain their forecast of Guidant entry in early 2006[63] and some even hint to the possibility of expediting the EU launch[64]. Only one analyst voices some reservations as to the possibility of staying within the announced timeline[65]. In sum, on balance, the view of the market was that, once Guidant had decided to call off the Champion Programme and focus all its resources on the Vision, and that the latter programme was on track and well supported by very robust clinical data, Guidant's entry in DES in early 2006 was a very credible date. And even endorsing the more conservative estimates of the more sceptical analysts, Guidant's delay on its foreseen time of entry would have been a matter of months (second quarter 2006). This is also the view of the great majority of competitors, with few exceptions[66].

110. Furthermore, […]*[…][67]. Therefore, Guidant had a strong interest in developing its DES product for European launch in early 2006.

111. The parties also contend that Guidant continues to face […] challenges in these areas […]*[68]. To the knowledge of the Commission, no disclosure of events likely to significantly jeopardise the timing of Guidant DES launch has been made to the financial community. And while J&J has publicly stated it would not provide updates on the state of play of Guidant DES programme pending the implementation of the merger, it is reasonable to assume that any occurrence entailing a serious delay in Guidant entry (and consequent threat to its earnings) on the DES market would have made public as it is the practice in the industry and as would have been required by securities legislation. Nor have the experts interviewed by the Commission signalled that Guidant was encountering additional hurdles likely to delay its entry in DES. Moreover, and perhaps more importantly, all the events that occurred after the announcement of the merger should be treated with caution. […]*

112. Finally, the issue of the relevance of Guidant's late entry into DES seems to be overstated by the parties. Whatever the delay Guidant would have encountered, its entry some time in 2006 would have occurred in proximity to Medtronic's entry. This, in all likelihood, would not have enabled any first mover advantage so to speak, all the more that in the DES market there are already two incumbent players. Moreover, it is clear from the market investigation that what matters most to physicians when it comes to drug eluting stents is their safety and efficacy and the solidity of the clinical data. For instance, when ranking the importance of the different parameters relevant for a successful new entry in DES, all the experts unanimously attribute the highest rank to the clinical data, while they all attribute the lowest mark or among the lowest to the factor next to enter[69]. In the same vein, in their reports analysts do not put any emphasis

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63 See Morgan Stanley, 27 January 2005, cited supra.

64 See Goldman Sachs, 28 January 2005, cited supra.

65 See Citigroup, 22 February 2005, cited supra, referring to the fact the trials have been expanded.

66 See Medtronic, White paper, Sorin, reply to questions n. 58-61 of the Questionnaire to competitors Interventional cardiology, I phase, folio 8130, dated 4 may 2005, Abbott, reply to questions n. 58-61 of the Questionnaire to competitors Interventional cardiology, I phase, folio 8081, dated 4 may 2005, Conor, minutes to the meeting with the Commission, folio 10381, dated 7 June 2005.

67 […]*

68 […]*

69 See replies to question n. 7 of the Questionnaire to *Experts* dated 4 May 2005.

on the fact Medtronic would be next to enter. In fact, some of them clearly state that, given the presence of two incumbents, what counts most for the purpose of a successful entry is the quality of the trials[70] .

113. On top of the factors which have been described above and are directly related to the DES, Guidant can also rely on an additional number of strategic assets which would have enhanced its prospect of success in DES:

i. Innovation and quality leadership: on this point, the evidence in the file is compelling, virtually all customers and competitors acknowledge that Guidant has always been at the forefront of innovation, and its products are of top quality[71].

ii. Formidable sales forces. On this aspect the evidence collected in the investigation is again unanimous. Guidant sales forces are considered the best, very well trained, customer minded, highly specialised[72].

iii. Patent portfolio. Among the new entrants Guidant is the only firm to have full access to the US market for stents thanks to its valuable patent portfolio. As it will be seen below, Guidant owns a number of key patents relating to the stent design (Lau) and the rapid exchange delivery system. To date, such IP rights, primarily those on Rapid exchange, constitute a significant impediment to enter the US market for stents to the extent that over 70% of US catheterization laboratories use RX exclusively, the remainder using alternative technologies such as Over The Wire (OTW)[73]. In Europe the rate of use of RX is instead close to 100%, as there is no patent protection on this technology. As a consequence, Guidant's patent portfolio does not seem to bring a serious threat to its competitors in Europe. However, in a global perspective, as said already, the strategic importance of the US market should not be totally neglected. In the light of the above, although the presence in the US market does not seem to be a necessary pre-requisite to competing in Europe, a strong foothold in the US market constitutes a competitive advantage for a firm with the ambition to compete on a global scale with other worldwide players such as J&J and Boston Scientific[74].

iv. Strong customer base in BMS and accessories. As a matter of fact the market leadership in BMS (EEA market share of around [25 - 35%]*) would significantly

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70 See Morgan Stanley, "*The 2005 Investors' Guide to Interventional Cardiology*".

71 See replies to question n. 49 of the questionnaire to customers Interventional cardiology, I phase, dated 16 March 2005, and replies to question n. 59 of the Questionnaire to competitors interventional cardiology I phase, dated 16 March 2005.

72 See replies to questions n. 35, 41, 45 and 49 of the questionnaire to customers Interventional cardiology, I phase, dated 16 March 2005, and replies to question n. 59 of the Questionnaire to competitors interventional cardiology I phase, dated 16 March 2005.

73 US Interventional Cardiology Markets (2003), Frost & Sullivan state "[i]n *2002, 65 percent of the U.S. market and 86 percent of the worldwide market were rapid exchange, while 31 percent of the U.S. market and 11 percent of the worldwide market were over-the-wire.*"

74 See Medtronic, White paper, cited supra; Abbott, replies to questions n. 50 to 52 of Questionnaire to competitors interventional cardiology I phase, folio 5987 (conf.), dated 30 March 2005; Conor, replies to Questionnaire to competitors interventional cardiology II phase, folio 8668, dated 18 May 2005; Sorin, replies to questions n. 50 to 52 of Questionnaire to competitors interventional cardiology I phase, folio 81830, dated 4 May 2005.

facilitate Guidant DES uptake vis-à-vis its customers. Even assuming, as the parties claim, that there is little loyalty in this market and the choice is entirely made on the quality and the price, it should be borne in mind that Guidant's BMS and delivery system, which would have been the base for its DES, are unanimously considered of excellent quality, and superior to those used both by J&J and Boston Scientific. It is reasonable to assume that, all other conditions being equal, that is in presence of a number of good DES on the market, Guidant would easily persuade its historic customers to buy its equally good, or better, DES[75]. […]*[76].

114. In the light of the above, the evidence in the file about Guidant prospect of success in the market for DES is mixed. On the one hand, the early stage of its trials, the small sample of patients being tested so far and the availability of only indirect (angiographic) parameters measuring the efficacy of its DES seem to suggest that unconditional confidence about Guidant's prospect of gaining the leadership of the DES market may be overstated. On the other hand, the extraordinary assets on which Guidant can rely, and the very positive comments expressed by the financial and medical community about its DES programme seem to indicate that, on balance, 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.

115. In any event, the evidence collected in the investigation also proves that the other new entrants will be likely to exert a sufficient competitive constraint on the market for the DES, compensating for the loss of competition resulting from J&J's acquisition of Guidant. Among the various new entrants in the market for DES, there are first and foremost two players capable of exerting significant competitive constraints in DES in Europe, namely Medtronic and Abbott.

(3) Medtronic

116. The evidence collected in the investigation indicates that Medtronic, together with Guidant, is well placed to enter the DES market successfully and gain a significant share in Europe. In particular, the investigation has confirmed that Medtronic can rely upon the following assets: i) excellent stent platform in cobalt chromium, flexible and deliverable, already established on the market; ii) good drug (its drug belongs to the Limus family and has been licensed by Abbott); iii) imminent entry in the DES market in Europe (the second clinical trial has been already performed, and entry is projected in the course of 2005); iv) good customer base, strong foothold in old generation stents (it is together with Guidant market leader in BMS in Europe) and accessories; v) sales forces.

117. Moreover, Medtronic's trials are very advanced, have been undergone on a large sample of patients, and their results are very positive. Indeed, Medtronic trials has already conducted two big trials, testing around 1000 patients. Moreover, based on those direct clinical parameters which better measure the DES performance (primarily the target vessel revascularisation and the target lesion revascularisation, i.e. the need to repeat the stenting procedure because due to a new blockage of the vessel), Medtronic's DES efficacy is by and large comparable if not better than other DES currently on the market.

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[75] See replies to questions n. 15-16 of Questionnaire to competitors, interventional cardiology, II phase, dated 4 may 2005.

[76] […]*

118. Some reservations have been voiced about Medtronic's prospect of full success in DES due to a higher than expected rate of late lumen loss (LL) recorded in its trials. In particular, Medtronic Endeavour LL is 0.62 mm[77], as opposed to 0.12 mm for Guidant[78], 0.17 for J&J[79] and 0.49 for Boston Scientific[80]. As previously explained, LL is an angiographic parameter which is meant to capture, inter alia, how much a treated vessel is candidate to restenosis.

119. On this point, the experts interviewed by the Commission voice some mild concerns, although to different degrees[81]. The most articulated reply appears to be that by Prof. Grube, who first reminds us that "Endeavor II was a positive trial in terms of clinical endpoints ; then, he states "The high likelihood of a higher late lumen loss is certainly of clinical relevance because there are evidence-based data demonstrating that a late of 0.60 mm is borderline and any late catch up over this value is likely to result in higher restenosis rates (…). He goes on" Therefore the late loss is still a very powerful parameter for proving effectiveness of a stent. (…) I would like to argue that late lumen loss is not the decisive parameter for the choice of DES, but will be a good parameter for long term success especially in high risk lesions subsets", […]*.

120. Conversely, as far as financial analysts are concerned, the views are rather favourable to Medtronic[82]. Some analysts do not really attach any importance to this problem. Others, while recognizing the issue, still maintain Medtronic can capture as much as 20% and more of the European markets based on the good safety data and the quality of the stent platform[83]; other analysts are more cautious: although they acknowledge the good clinical data and safety profile, they project Medtronic at 10-15%[84], or around 15%[85].

121. […]*.

122. In sum, the evidence collected in the investigation with respect to Medtronic's prospect of success is also mixed. Medtronic's entry in the European market for DES appears to be imminent. Moreover, Medtronic has all the assets to be successful in this market, above all a DES whose good performance is supported by positive clinical data. The market has also signalled the issue of Medtronic DES high late lumen as a potential problem over the time. However, the prevailing view is that this issue may ultimately have only modest negative implications, and essentially in the long term.

123. In the light of the above, it can be concluded that Medtronic is likely to exert a significant competitive constraint in the market for DES in Europe in the short/mid run.

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77 In stent late loss, Endeavour II trials, 9 months results.

78 In stent late loss, Spirit First trial, measured at 6 months.

79 In stent late loss, Sirius trial, measured at 8 months.

80 In stent late loss, Taxus V trial, measured at 9 months.

81 See replies to question n. 4 of Questionnaire to *Experts, dated 4 May 2005*.

82 See analysts reports on Medtronic, in Guidant submission, folio 5734, dated 23/03/2005, and Medtronic submission, folio 7284, dated 1 April 2005.

83 See JP Morgan and Bernstein, in Guidant submission, ibidem.

84 See Morgan Stanley and Bearn Sterns, 7 March 2005, in Medtronic submission, cited supra.

85 See Merrill Lynch, Goldman Sachs, Citygroup, 7 March 2005, in Medtronic submission, ibidem.

(4) Abbott

124. As regards Abbott, the evidence collected in the investigation shows that it should be regarded as a credible entrant with a long term future in the market for DES in Europe (entry foreseen in 1st quarter 2007), although the prospect of becoming a leading player is still untested.

125. Abbott is a big company with significant financial strength (US […]* revenues in 2004), a deep expertise in pharmaceuticals (an important asset for the development of the next generation DES), and commercial experience with hospitals. This could enable it to eventually enter the European markets for cardiac medical devices on a significant scale. The company seems to be strongly committed to enter the IC market as it is proved for instance by its massive investments in the ongoing DES programme. Abbott is the first DES competitor to have developed its own drug and unique polymers, coating and application process. Abbott has also developed a stent platform based on a proprietary design. The company is also developing its sales forces to support the expansion of the business. In terms of numbers, its direct sales forces in Europe are comparable to Medtronic.

126. As to the view of the market about Abbott's DES, the comments collected in the investigation are positive, although there is little compelling evidence supporting such views. It seems that Abbott can rely upon the following assets: i) a novel stent platform, based on a proprietary original design, very flexible and visible; ii) a good drug, the ABT 578, which has also been licensed to Medtronic. This drug belongs to the Limus family, and thus is potentially effective to treat restenosis; iii) A good drug releasing mechanism. On this point, the opinion of the market is that Abbott has put in place a more gradual mechanism of release with the addition of a 'pharma' coat which would result in a better performance than Medtronic's stent[86].

127. In their comments, the experts by and large share the above view. Most of the experts confirm that Abbott's DES seems to be very promising, although they note that there are no clinical mid or long term results available and in particular no compelling data yet on the efficacy of the drug (see opinions of Dr. Grube, El Khoury, Chevalier, Morice)[87].

128. The comments collected in the analysts reports are along the same lines. There are in general great expectations of Abbott's programme, although no solid pieces of clinical data are available to substantiate these views. In short, analysts tend to regard Abbott as a possible outsider capable in principle of obtaining a great performance[88].

129. Abbott has also the additional handicap of lacking a track record and experience in coronary stents. For instance, its bare metal stent, which mounts the same platform that will be used for the DES, has just been launched in Europe and it is still largely untested. Moreover, in Europe Abbott has a very little customer base in the area of IC to leverage for the purpose of the development of its future DES business. On average, Abbott holds a market share of around [1-10%]* in the European market.

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86 See […]*; see also Morgan Stanley, *The 2005 Investors' Guide to Interventional Cardiology*", 2005, p. 27.

87 See replies to questions 14-15 of Questionnaire to *Experts,* dated 4 May 2005.

88 See Morgan Stanley, "*The 2005 Investors' Guide to Interventional Cardiology*".

130. Finally, in favour of Abbott's unreserved commitment to enter the DES market and become a credible player, it should be noted that Abbott is the beneficiary of the package license of IP rights granted by the parties in order to meet the competition concerns identified by the US FTC in the US market[89]. As a result of this, in particular the full access to RX technology, Abbott's prospect for future expansion in the US market for DES becomes sufficiently credible.

131. In conclusion, taking all the above factors into account, it appears that, while it would be rather speculative to predict that Abbott will play a leading role in the DES market, it can be confidently anticipated that Abbott will most likely be able to exert at least a non negligible competitive constraint in the market for DES in Europe.

(f) The fringe players

132. On top of the firms mentioned above, there are also other smaller medical devices suppliers which are entering the market for DES in Europe, mainly Conor/Biotronik and Sorin.

(1) Conor/Biotronik

133. As regards Conor, the investigation seems to indicate that it is theoretically well placed to enter the DES market with a first-rate DES. In particular, Conor has i) a good quality stent made of cobalt chromium which provides for good radiopacity and flexibility; ii) a novel stent design which uses drug reservoirs that elude the drug rather than the surface coating method used by other companies; iii) it uses the paclitaxel drug (also used by Boston Scientific). However, unlike Boston Scientific's Taxus Conor's stent is said to elude this drug in a better way because of the use of reservoirs which direct the drug directly into the vessel wall. iv) Conor's trials so far have provided very positive clinical data. Its DES performance is comparable to the DES currently on the market, perhaps even better than Taxus. v) Conor's entry in Europe should be imminent, as it forecasts to enter the market in the second half of 2005[90].

134. However, Conor has no business in Europe, and has appointed the German company Biotronik as its exclusive distributor for Europe. Biotronik is a supplier of medical devices and systems for diagnostics and therapy of cardiovascular disorders; this includes coronary and peripheral BMS.

135. Table B below provides BMS market shares of Sorin and Biotronik across Europe. The table is well illustrative of the presence of these players in the area of IC across European countries.

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89 In its assessment of the transaction, the US FTC has concluded that the merger may give rise to competition concerns in the area of DES in the US, due to the fact the parties will have a strong patent portfolio, in particular they will control the rapid exchange delivery technology, access to which is important to properly compete in the market for DES. In order to address these concerns, the FTC has requested that a third party competitor be granted by the parties the necessary IP licenses to be able to fully compete in the US market for DES.

90 Conor press release dated 23 March 2005.

Table B

BMS	Sorin	Biotronic
Austria	[10%-15%]	0
Belgium/Luxemb	[0%-10%]	0
Cyprus	0	0
Czech Rep.	0	[0%-10%]
Denmark	0	0
Estonia	0	0
Finland	0	0
France	[0%-10%]	0
Germany	[0%-10%]	[0%-10%]
Greece	0	[0%-10%]
Hungary	0	0
Ireland	0	0
Italy	[0%-10%]	0
Latvia	0	0
Lithuania	5	0
Malta	0	[35%-45%]
Netherlands	0	0
Poland	0	0
Portugal	0	0
Slovakia	0	0
Slovenia	0	0
Spain	[0%-10%]	0
Sweden	[0%-10%]	0
UK	0	0

Market shares in volume. Source: market investigation.

136. As can be seen from the table, Biotronik has an extremely small business in BMS, essentially concentrated in Germany and few other countries. The experts interviewed by the Commission, while expressing some positive comments about Conor's DES, doubt that this firm could establish itself as a strong competitive force in DES. One comments that Conor and Biotronik are not in the same league as the big US players[91]. Some point to the fact that neither Conor, nor Biotronik, have proven expertise in BMS and in more general terms in IC[92]. In the same vein, financial analysts regard Conor as a niche player[93].

137. Based on the above, it appears that Conor/Biotronik lack a minimal critical mass in terms of size, as well as the geographic coverage in Europe to be able to exert a significant competitive constraint in the market for DES vis-à-vis large multinationals multibillion companies across Europe. That said, Conor/Biotronik may be able to bring some additional competition in those domestic markets in which it is well established.

(2) Sorin

138. As regards Sorin, it is the largest European vascular devices company, with a worldwide turnover of about Euro […]*. Sorin has already received approval and launched its DES on the European market, although its presence in terms of market shares is almost imperceptible. On Sorin's DES programme, the evidence collected in the investigation is rather mixed. Some experts express positive comments about Sorin (Morice, Grube). Others, instead voice reservations […]*.

91 See Dr Chevalier opinion.

92 See Dr Morice and Dr Khoury opinions.

93 See Guidant submission on Conor.

139. In a market where size, reputation, innovation, financial means and geographic reach matter, Sorin does not seem well placed to secure a significant competitive constraint towards the market leaders in the whole of Europe, as it lacks some of the above assets. That said, like for Conor/Biotronik, Sorin may be able to bring additional competition in those domestic markets in which it is well established.

(g) Intellectual Property Rights situation

140. During the investigation, some competitors argued that as a result of the merger the parties would hold a very valuable portfolio of patents in the area of coronary stents, primarily in the US, and to a lesser extent in the EU. As a consequence, entry in the market for DES would become extremely difficult. Moreover, it was also argued that the merger would reduce the parties' incentives to license key patents to other players. Finally, it was claimed that because of the problems being encountered in the US, competitors would be also forced to exit the European market for DES.

(1) The parties' patent portfolio

141. The market investigation has ascertained that each of the parties owns a number of key patents in the area of coronary stents. J&J owns in the US the Palmaz and Schatz patents, which cover balloon expandable stents (and expire in November 2005 and March 2010, respectively). The European patent, based on the same disclosure, is limited to certain balloon expandable stents having only a specific geometric design. J&J also owns the Wright and Falotico patents covering the use of certain drugs in DES and the Pinchuk and Fontirroche patents relating to balloon catheters

142. Also Guidant owns a number of key patents, primarily relating to the stent design (Lau) and the rapid exchange delivery system (Yock, Yock Horzewski and Lau-RX).

143. The only other companies with the right to commercialize RX delivery systems are Boston Scientific[94] and J&J[95]. To date, such IP rights, primarily those on Rapid exchange, constitute a significant impediment to enter the US market for stents to the extent they have become the standard of care. The last of the RX patents is due to expire in 2011[96]. In the US over 70% of US catheterization laboratories use RX exclusively, the remainder using Over The Wire technology[97]. In Europe the rate of use of RX is instead close to 100%, as there is no patent protection on this technology.

144. Table C below summarises certain of the most important patent families owned by the parties[98]:

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94 […]*.

95 […]* See Medtronic White paper.

96 Bonzel patent (held by Boston Scientific) in late 2005, Yock patent (held by Guidant) in 2008, Lau RX patent (held by Guidant) in 2011.

97 US Interventional Cardiology Markets (2003), Frost & Sullivan state "[i]n *2002, 65 percent of the U.S. market and 86 percent of the worldwide market were rapid exchange, while 31 percent of the U.S. market and 11 percent of the worldwide market were over-the-wire.*"

98 The scope of these patents is much larger in the US than in Europe **Yock:** there are ten issued US Yock patents; there are no European Yock patents. **Lau RX**: there are seven issued US Lau RX patents; there is only one European counterpart to these patents […]*. **Yock-Horzewski:** there are several US Yock-Horzewski patents and only one European one. **Palmaz-Shatz**: […]* companies have sold stents in Europe

Table C

	Delivery system	Stent Design	Drug / polymer	Balloon Catheter
J&J		Palmaz Schatz	Wright Falotico	Pinchuk Fontirroche
Guidant	Yock Yock – Horzewski Lau RX	Lau		

145. As well as the ownership of the various patent families outlined above, the merging parties and their competitors own the right to use certain patents and technology as a result of licenses from third parties (or from each other). Some of these licenses have been entered into in order to avoid or terminate litigation.

(2) Patent litigation

146. The market investigation has also shown that patent disputes and litigation are commonplace in the BMS and DES markets in the USA. They are in some sense a cost of doing business in the market and any player in the market can expect litigation. Patent disputes are often resolved through cross-licensing agreements between competitors. Court actions can also result in the award of damages or, less frequently, in injunctions against the infringing products.

147. By way of example, it is precisely following a court injunction in 2001 that Medtronic has been deprived of access in the US to the key patented technology of *rapid exchange*. The effect of this on the US market is that the RX delivery method predominates (over 70% of stenting procedures are carried out using RX technology) but that a sizeable minority (around 30%) of stents are delivered using alternative technologies (primarily OTW) offered by competitors without access to RX.

(3) The intellectual property landscape in Europe

148. However, the market investigation has also revealed that the patent landscape in Europe is very different from the US for a number of reasons: first the patent coverage of these devices is much narrower than in the US, for example some primary patents on RX technology have never been granted in Europe; second, many interventional cardiology device patents have earlier expiry dates in the EEA; third, European courts tend to be less interventionist than their US counterparts and more sensitive to public interest arguments; moreover, injunctions are rarer in the EU than in the US and while in the EU some countries offer the option of a compulsory license to an infringer, in the US such a license is generally not available. Finally, in the USA an injunction under a US patent in any federal court is effective throughout the USA whereas to achieve the same effect in the EU one would need to initiate country-by-country infringement actions. Most

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while avoiding this patent. **Lau**: there are nineteen issued US patents that are part of the US Lau patent family; there are two European patents that are counterparts to the US ones – however these two patents are divisionals of another European Lau patent that was revoked by the European patent office on 24 October 2000. **Wright**: patent protection has been granted in the US; in Europe J&J's application is allowed pending an opposition procedure started in 2004.**Falotico**: patent protection has been granted in the US; in Europe an application has been filed with the EPO but not yet granted.

competitors have indeed confirmed in the market investigation that in Europe patents should not be regarded as a major impediment to operate in the field of coronary stents. Based on the above, it can be concluded that there is no significant litigation risk in Europe that can prevent competitors in their effort to market their products in the EEA.

(4) The impact of the US Intellectual Property rights situation on the European DES markets

149. The Commission has then considered, in turn, the competitors' claims that i) the merger removes the parties' incentives to license their IP rights to other stent suppliers; ii) there is a link between the US market and the EU market in the sense that the inability to fully access the US market would impair [third parties]* long term capability to act as viable competitors in Europe. To do so, the Commission has co-operated with the US Federal Trade Commission in the analysis of the US patent and litigation landscape.

(i) **The change in Guidant's attitude towards a settlement agreement[…]***

150. With respect to the first point, according to Medtronic the merger has reduced the incentives of Guidant to license IP rights to other stent suppliers […]*. Following the merger, the parties would have no more incentives to settle as they would rely upon a broader patent portfolio less exposed to litigation […]*.

151. To support its claim that the merger removes the incentives of Guidant to reach a settlement with it on intellectual property rights, Medtronic has provided an economic modelling study from the consultant Lexecon […]*.

152. After close examination of these arguments, it appears that Medtronic claims are not supported by sufficiently solid evidence.

153. To begin with, it should be noted that for harm to be proven as a consequence of the merger, it is not sufficient to claim that the merger reduces Guidant's incentives to settle, it is also necessary to demonstrate that the reduction in incentives will be such as to make Guidant switch from a 'soft line' (open to settlement) attitude pre-merger to a hard line (not open to settlement) attitude post-merger […]*. However, as a matter of fact, Medtronic has not provided any piece of evidence showing that in recent times Guidant had the intention to include […]* patents in any settlement. […]*

154. […]*

155. […]*

(ii) **The link between presence on the US DES market and the EEA DES markets[…]***

156. As to the link between the US and Europe, and the alleged negative spill-over effects that [third parties]* would suffer in the European market for DES as a consequence of […]* problems in the US, it should be noted that, [third parties]* claim […]* seems overstated as regards both the alleged negative effects on [third parties]* sales and the duration of such effects.

157. Regarding the Lau stent design patents, Medtronic has to date been not impeded from commercialising its stents due to these patents, despite the unfavourable outcome of the litigation.[99]

158. Regarding the patents on RX, while it is a fact that such a technology is preferred by the great majority of US physicians, around 30% of US stenting procedures are still carried out using the alternative technologies to RX. Moreover, after the 2001 ruling, Medtronic has been actively developing new delivery systems that do not appear to be infringing on Guidant (and Boston Scientific) patents and may well enable Medtronic to increase its sales, in particular once its new DES will be available for commercialisation in the US […]*.

159. Equally so, Medtronic's claim that lack of access to RX will last for a period up to 2015[100] seems rather extreme, and based on a number of speculative and unlikely assumptions. Importantly, the injunction to market products based on RX technology will be lifted once the Yock patents (the core patents protecting the RX) expire in 2008. Competitors would then be able to market products based on RX technology, although they could be sued by Guidant because of breach of the Lau RX patents. The latter however have never been tested in court and a number of respondents to the market inquiry doubted their validity. It is therefore impossible to predict whether Guidant would be able to block any competitor from commercialising RX based products in the US based on the Lau RX patents after 2008 […]*.

160. In fact, in its assumptions Medtronic hardly takes into account the typical features of the interventional cardiology business, which are such that companies do regularly develop and market products that risk infringing on competitors' IP rights portfolio; that injunctions are not issued very often even in the US; and that, given the importance that innovation plays in the industry, the IP landscape can change significantly from the present day to 2009, taking directions that cannot be predicted ex ante.

161. Aside from the above, most importantly, it remains unproven how the hurdles [third parties]* would encounter in the US due to […] IP rights problems could cause a direct and tangible negative effect on [third parties]* DES sales in Europe within a close and foreseeable timeline.

162. To begin with, it should be reminded that, as a matter of fact, the merger cannot endanger the commercialisation of [third parties]* DES ([…]*), which in all likelihood […] going to be launched in the EEA […]*. In this respect, [third parties]* provided […] estimate figures […]*.

163. However, [third parties]* estimates are again based on a number of […]* speculative assumptions whose veracity it is appropriate to question. […]*

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99 The 2005 ruling asserting that some of Medtronic's coronary stents infringe Guidant's Lau patents does not appear to have had any direct impact on the offer of Medtronic products and the company has announced that it will appeal the verdict. It is not for the Commission to prejudge the outcome of this patent litigation by replacing the verdict of a judge with its assessment; any conclusion based on such basis would be highly speculative.

100 Medtronic has pointed out that Guidant may seek an extension to the validity of its patents and that the extension could be granted for up to four years, as a result of which it could be impaired from selling products based on RX technology for a period up to 2015 in the worst case scenario.

164. Based on the elements described above, [third parties]* not shown convincingly that direct and significant adverse effects on [third parties]* sales in Europe will materialise as a consequence of such hurdles.

(h) Conclusions – Non coordinated adverse effects in the market for DES

165. In conclusion, the concentration results in the elimination of one of the strongest new entrants in the market for DES, which, absent the merger, would have acted as a major competitive constraint in such a market. However, the investigation shows as well that the other new entrants, primarily Medtronic and Abbott, and to a lesser extent Sorin and Conor/Biotronik are likely to compensate for the loss of competition resulting from Guidant's exit from the marketplace due to the merger and exert a sufficiently significant competitive constraint in Europe. Based on the above, it is reasonably expected that the concentration will not significantly impede effective competition in the Common market and the EEA for DES.

2) Bare Metal Stents

166. As regards the market for bare metal stents on its own, as said before, the rate of penetration of DES in the EU is not as high as in the US. While in the US BMS have almost disappeared, in Europe they are still important and count for roughly 40% of the total EEA market of coronary stents in value (€ 334 million in 2004).

167. As to the competitive landscape, the investigation has confirmed that in the European market a certain degree of competition is recorded and prices have been progressively declining over the last years. Besides the big four, a number of new players (Sorin, Biotronik, Terumo, B.Braun, Angiotech) have entered the market, supplying products of acceptable quality at cheaper price. New entry in the European market has been possible due to the fact patent protection of medical devices is much narrower than in the US. This has enabled the new entrants to have access to Rapid eXchange, the standard technology used by physicians for delivering the stents, as well as design around the major patents owned by the big four which protect the stent platform and design.

Table D

BMS	J&J	GDT	J&J+ GDT	BSX	MDT	ABT	Other
Austria	[<5]*	[30-40]*	[30-40]*	[0-10]*	[30-40]*	[<5]*	[20-30]*
Belgium/Luxemb	[<5]*	[50-60]*	[50-60]*	[10-20]*	[20-30]*	[<5]*	[0-10]*
Cyprus	[<5]*	[20-30]*	[20-30]*	[10-20]*	[50-60]*	[<5]*	[<5]*
Czech Rep.	[<5]*	[0-10]*	[10– 20]*	[0-10]*	[10– 20]*	[10– 20]*	[50-60]*
Denmark	[10–20]*	[30-40]*	[50-60]*	[10– 20]*	[30-40]*	[<5]*	[0-10]*
Estonia	[10– 20]*	[<5]*	[20-30]*	[40-50]*	[30-40]*	[0-10]*	[0-10]*
Finland	[0-10]*	[0-10]*	[10– 20]*	[30-40]*	[50-60]*	[<5]*	[<5]*
France	[<5]*	[30-40]*	[30-40]*	[10– 20]*	[30-40]*	[<5]*	[10– 20]*
Germany	[0-10]*	[30-40]*	[40-50]*	[0-10]*	[30-40]*	[<5]*	[10– 20]*
Greece	[<5]*	[20-30]*	[20-30]*	[0-10]*	[30-40]*	[<5]*	[20-30]*
Hungary	[0-10]*	[[10-20]*	[20-30]*	[20-30]*	[40-50]*	[<5]*	[0-10]*
Ireland	[<5]*	[<5]*	[<5]*	[10– 20]*	[50-60]*	[10– 20]*	[10– 20]*
Italy	[<5]*	[30-40]*	[40-50]*	[10– 20]*	[30-40]*	[<5]*	[0-10]*
Latvia	[40-50]*	[<5]*	[40-50]*	[20-30]*	[10– 20]*	[<5]*	[0-10]*
Lithuania	[10-20]*	[<5]*	[10-20]*	[40-50]*	[20-30]*	[0-10]*	[0-10]*
Malta	[<5]*	[10-20]*	[10-20]*	[<5]*	[<5]*	[<5]*	[80-90]*
Netherlands	[<5]*	[30-40]*	[30-40]*	[10-20]*	[40-50]*	[<5]*	[0-10]*
Poland	[30-40]*	[20-30]*	[50-60]*	[10-20]*	[10-20]*	[<5]*	[0-10]*
Portugal	[<5]*	[30-40]*	[30-40]*	[0-10]*	[40-50]*	[<5]*	[0-10]*

BMS	J&J	GDT	J&J+ GDT	BSX	MDT	ABT	Other
Slovakia	[<5]*	[0-10]*	[10-20]*	[0-10]*	[40-50]*	[20-30]*	[10-20]*
Slovenia	[<5]*	[20-30]*	[20-30]*	[20-30]*	[10-20]*	[40-50]*	[<5]*
Spain	[<5]*	[40-50]*	[40-50]*	[0-10]*	[30-40]*	[<5]*	[0-10]*
Sweden	[<5]*	[20-30]*	[20-30]*	[20-30]*	[20-30]*	[<5]*	[10-20]*
UK	[<5]*	[30-40]*	[40-50]*	[10-20]*	[40-50]*	[<5]*	[<5]*

Source: parties' data validated by the market investigation; market shares in value.
NB: GDT: Guidant; BSX: Boston Scientific; MDT: Medtronic; ABT: Abbott

168. In the market for BMS Guidant is one of the two leading suppliers in Europe, with a share of [30-35%]* in 2004. Medtronic has an equivalent market position, while J&J has a limited presence in Europe, around [0-10%]. The above market shares are by and large representative of the situation in most domestic markets of the EEA. Moreover J&J sales have been decreasing steadily over the last two years […].* The investigation has also confirmed that Guidant and J&J are not perceived as close BMS competitors, and that, more importantly, J&J sales are progressively and irreversibly shrinking, […].* As a consequence, the overlaps are in most countries very small.

169. In conclusion, based on the investigation it appears that Guidant and J&J are not close BMS competitors. J&J […]* lost market shares over the last three years, and in most instances retains a tiny position in few domestic markets. Post-transaction, there will remain a number of significant BMS competitors in the EEA, including one of the two leaders, Medtronic, and Boston Scientific, plus some fringe players. Neither these suppliers, nor the many other BMS suppliers face any significant barriers to expansion. In the light of the above, the transaction will therefore not result in a significant impediment to effective competition in the common market and the EEA for BMS.

3) IC accessories

170. The market of accessories consists essentially of PTCA balloon catheters, steerable guidewires and guiding catheters. In value, this market is small relative to the market for coronary stents, in Europe it amounts to less than 30% of the total value of the market for interventional cardiology devices. Taking each individual segment, PTCA balloon catheters are the most important market in value and count for […]* in the EEA, guidewires come second with […]*, and last come the guiding catheters with […]*. At national level, virtually all of these markets have a limited size. For instance, in Germany, which is by far the largest national market of the EU, the market for PTCA balloon is about […]* while total sales for guiding catheters are about […]*.

171. The market for accessories shows also some specific features likely to influence the competitive dynamics of the market place. First, it appears from the market investigation that accessories tend to be more and more "commodity" like items, to the extent they are relatively simple and homogeneous products. As a consequence, compared to the market for stents, there is less differentiation and stronger price competition between a large number of suppliers, including some local players. On the other hand, the trend towards commoditisation is perhaps less accentuated for some of these items, such as in particular guidewires, where quality remains one of the key criteria driving customers' choice. It is telling that Guidant is the undisputed leader for guidewires due to the superior quality and flexibility of its products.

172. Second, interventional cardiology accessories are low margin products, dependent to some extent upon the primary markets for stents. In particular, it has been argued by

some respondents to the Commission market investigation that package deals bundling accessories and stents are a recurrent practice, with the latter item playing a decisive role for the success of the offering.

173. That said, based on the data provided by the parties on a country basis and the information collected in the investigation, it appears that the correlation between stents and accessories in most countries of the EU is not particularly strong, given that the parties and their competitors' market shares across various segments of the interventional cardiology, i.e. accessories and stents, are pretty uneven. On top of that, some market shares fluctuations within each segment are also recorded over the time. This is explained by the fact that sourcing through formal tendering and by single item is also common, thus creating room for contestability.

(1) Guiding catheters and PTCA balloon catheters

174. As to the competitive landscape pertaining to Guiding catheters and PTCA balloon catheters, the parties' position in the various segments is somehow complementary, although non insignificant overlaps are recorded in some markets. In particular, with respect to guiding catheters, J&J is the number two player in the EEA with [25-35%]*, while Guidant is a small player with [0-10%]*. Market leader is Medtronic with [35-45%]*.

175. In PTCA Guidant and J&J have a share of respectively [15-25%]* and [5-15%]*, while Boston Scientific is market leader with [35-45%]*.

176. The above market shares are by and large representative of the situation at national level in the EEA, although in some countries more significant horizontal overlaps are indeed recorded. Also as regards the two major competitors, namely Medtronic and Boston, their market shares in the EEA more or less accurately reflect their positions on a country basis. As to other competitors, Abbott is also more or less active across Europe with a share on average of about [5-15%]*, although it cannot count on a complete product range. Finally, there are the already mentioned local players which are generally focused only in some regions of Europe. For ex., Sorin is more present in the Mediterranean countries of the EU, while firms like Biotronik, Braun, Terumo, are generally more active in central European countries. However, these remain niche players with market shares in principle hardly ever above 5%.

177. As regards more specifically the impact of the transaction on the market of accessories on a country basis, the situation is the following:

178. As to guiding catheters, the parties' combined market shares go up to [65-75%]* and above in only two countries, while in the rest of the countries mostly affected combined market shares are around 40-50% and the increment is generally negligible: see Table E below.

Table E

Member State	J&J in %	Guidant in %	Combined market share in %	Post HHI	Δ
Austria	**[35-45]***	**[0-10]***	**[45-55]***	**4,445**	**760**

Member State	J&J in %	Guidant in %	Combined market share in %	Post HHI	Δ
France	**[35-45]***	**[0-10]***	**[35-45]***	**4,650**	**288**
Germany	**[35-45]***	**[0-10]***	**[45-55]***	**4,109**	**560**
Greece	**[45-55]***	**[0-10]***	**[55-65]***	**4,901**	**714**
Portugal	**[25-35]***	**[5-15]***	**[35-45]***	**3,589**	**754**
Slovakia	**[55-65]***	**[25-35]***	**[85-95]***	**7,617**	**3,630**
Slovenia	**[65-75]***	**[0-10]***	**[75-85]***	**6,013**	**852**
UK	**[25-35]***	**[0-10]***	**[35-45]***	**3,381**	**558**

Source: Parties' data validated by the market investigation.

179. As to PTCA balloon catheters, the parties' combined market shares are around or above 40%, with an increment of at least 5% only in Austria, Malta, Slovakia, Czech Republic and The Netherlands: see Table F below.

Table F

Member State	J&J in %	Guidant in %	Combined market share in %	Post HHI	Δ
Austria	**[5-15]***	**[25-35]***	**[35-45]***	**2,948**	**868**
Czech Rep.	**[25-35]***	**[5-15]***	**[35-45]***	**2,556**	**702**
Malta	**[75-85]***	**[5-15]***	**[85-95]***	**7,738**	**820**
Netherlands	**[5-15]***	**[25-35]***	**[35-45]***	**3,412**	**576**
Slovakia	**[5-15]***	**[55-65]***	**[55-65]***	**4,487**	**472**

Source: Parties' data validated by the market investigation.

180. However, based on the evidence collected in the market investigation it appears that there are no concerns arising out of the transaction in the above markets due to several reasons.

181. With respect to PTCA balloon catheters, Boston Scientific will remain the leading supplier and the leading innovator, with market shares on average above [35-45%]*. Medtronic is also a strong competitor, with EEA market shares well above [5-15%]* in most countries of the EU, equivalent if not higher than J&J. In guiding catheters Medtronic will remain the leading supplier throughout the EEA with market shares around [40-50%]*. Boston Scientific is also an important supplier, with a EEA share of around [10-20%]*. Guidant has a very small share of around [0-10%]* and adds very little to J&J position. On top of that, in both markets, there are also other players who constitute an additional source of competition.

182. Moreover, as noted already, these accessories are rather homogeneous products. As a consequence, competitors are not output-constrained and do not face barriers to expansion or repositioning.

183. In light of the above, the merger does not give rise to a significant impediment of effective competition in the common markets and the EEA for PTCA balloon catheters and guiding catheters.

(2) Steerable guidewires

184. In steerable guidewires, with some exceptions, 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 [65-75%]* and even [75-85%]*: see Table G below.

Table G

Member State	J&J in %	Guidant in %	Combined market share in %	Post HHI	Δ
Austria	**[5-15]***	**[65-75]***	**[75-85]***	**6661**	**1518**
Belgium/Luxembourg	**[5-15]***	**[55-65]***	**[65-75]***	**5494**	**1080**
Czech Rep.	**[55-65]***	**[25-35]***	**[85-95]***	**9035**	**4292**
Denmark	**[5-15]***	**[35-45]***	**[55-65]***	**4631**	**1148**
France	**[5-15]***	**[75-85]***	**[75-85]***	**6691**	**750**
Germany	**[5-15]***	**[65-75]***	**[65-75]***	**5322**	**650**
Greece	**[15-25]***	**[55-65]***	**[75-85]***	**9038**	**1700**
Hungary	**[5-15]***	**[25-35]***	**[35-45]***	**3558**	**576**
Ireland	**[5-15]***	**[55-65]***	**[55-65]***	**5818**	**414**
Italy	**[5-15]***	**[65-75]***	**[65-75]***	**5225**	**840**
Poland	**[5-15]***	**[75-85]***	**[90-100]***	**9802**	**1780**
Portugal	**[5-15]***	**[65-75]***	**[65-75]***	**4631**	**784**
Slovakia	**[5-15]***	**[75-85]***	**[75-85]***	**7987**	**516**
Sweden	**[5-15]***	**[35-45]***	**[35-45]***	**4696**	**490**
UK	**[5-15]***	**[55-65]***	**[55-65]***	**4812**	**714**
EC	**[5-15]***	**[55-65]***	**[65-75]***	**5597**	**896**

Source: Parties' data validated by the market investigation. Data in value, except for HHI (volume data)

(a) The parties' claims

185. The parties argue that market shares are not reflective of market power in the interventional cardiology sector, that barriers to entry are low and hospitals are able to exercise buyer power so as to be able to resist unilateral increases in price. Moreover, guide-wires are differentiated products, and J&J and Guidant are not each other's closest competitor. They therefore argue that the Commission should not be concerned about the significant accretion of market shares in the steerable guidewire market which will result from the merger. They argue that highly innovative products win customer acclaim and topple the market leader quickly so that high market shares may only be a transitory phenomenon.

186. The parties further argue that, post merger, there remains sufficient competition on the market for steerable guidewires because Boston Scientific, which the parties state is Guidant's closest competitor, continues to be present in this market and can be expected to grow its market share, as can the other small players already active in this market such as Biotronik, so that, even if there were to be any unilateral price increases, customers would have sufficient competitive alternatives to J&J and Guidant.

(b) The competitive landscape

187. The market investigation has provided a different picture. To begin with, it is clear from the market shares set out above that the merger will result in a quasi monopoly situation for steerable guidewires in some Member States. While in certain cases the increment of market share is small (generally a relatively small J&J share is being added to a very high Guidant share although this is not the case in all Member States), the accretion remains on average non negligible especially when added to a very large market share.

188. In the vast majority of Member States the merger represents the addition of the number one player, Guidant, with the number three player, J&J. This is the case for Austria ([75-85%]* combined share, number two player Boston Scientific has [10-20%]*), Belgium/ Luxembourg ([65-75%]* combined share, number two player Boston Scientific has [25-35]%), France ([75-85%]* combined share, number two player Boston Scientific has [15-25%]*), Germany ([65-75%]* combined share, number two player Boston Scientific has [15-25%]*), Hungary ([35-45%]* combined share, number two player Boston Scientific has [15-25%]*), Ireland ([55-65%]* combined share, number two player Boston Scientific has [25-35%]*), Italy ([65-75%]* combined share, number two player Boston Scientific has [15-25%]*), Netherlands ([75-85%]* combined share, number two player Boston Scientific has [15-25%]*), Portugal ([65-75%]* combined share, number two player Boston Scientific has [15-25%]*), Slovakia ([75-85%]* combined share, number two player Boston Scientific has [15-25%]*), Spain ([75-85%]* combined share, number two player Boston Scientific has [5-15%]*) and UK ([60-70%] combined share, number two player Boston Scientific has [25-35%]*). This illustrates that the merger results in many market shares of around 70% – 80% with only one significant competitor left, often with a market share several times smaller than the merging entity.

189. In the Czech Republic, Greece, Poland and Malta the merger represents the addition of the number one and the number two players resulting in market shares starting at [75-85%]* (Greece) and reaching [90-100%]* (Malta).

190. It is clear from the above that the addition of J&J's market share to Guidant's very significant market shares reinforces Guidant's uncontested leadership in the steerable guidewire markets.

(c) Guidant strength

191. The accretion in market share is all the more important because of Guidant's particular strength in guidewires. The market investigation revealed, and competitors stated, that, of the various interventional cardiology accessories, guidewires are the ones on which physicians express a particular preference – they get used to the feel of how the wire operates during the procedure. In particular, Guidant's steerable guidewire was perceived by customers as being of superior quality to other guidewires. Many customers stated that the Guidant steerable guidewire was their guidewire of choice. Other customers stated that Guidant's guidewires were much better than the others on the market[101]. Further, many customers perceived Guidant as being a company with a strong brand[102] and quality leadership[103]. This suggests that customers value the Guidant

[101] Hospitais da Universidade de Coimbra, folio 5805

[102] London Chest Hospital, folio 7734

steerable guidewire product because of its superior nature but are also loyal to the Guidant brand because of its perception as a mark of quality and reliability. Overall this customer preference is clearly illustrated by Guidant's very high market share.

192. That said, the market investigation also revealed that guidewires in general are only moderately differentiated products. Customers perceived them to be, and competitors described them as, being 'broadly interchangeable'[104] with no significant technical differences. As a consequence, the closeness of substitution does not play a decisive role for the purpose of the analysis, while market shares remain a good indicator of market power.

193. Based on the above, in response to an increase in price post merger, customers could be expected to switch to the remaining competitors in proportion to their market shares. However, the market shares mentioned above show that, other than Boston Scientific, there are no significant players in the market for steerable guidewires. Not to mention those countries in which the parties are number one and two and Boston Scientific is hardly present.

194. In sum, post merger there is clearly a reduction in customers' competitive alternatives. Were the merged entity to raise prices post merger, either no alternative, or, only Boston Scientific would act as a competitor; however, Boston Scientific alone would not provide a sufficient competitive constraint upon it such as to remedy the significant impediment to effective competition produced as a result of the merger.

195. The parties also argue that, besides Boston Scientific, there are a host of small competitors who could enter the market within a relative short time scale or expand their sales in response to a price increase. However, the competitive landscape, as revealed by the market investigation, is not such as to lend credibility to the argument that other competitors are ready and able to enter the market – potentially on an EEA wide basis at short notice in response to an increase in demand such as to act as a sufficient constraint on the merged entity. As to the competitors already present, these are extremely small players which have failed so far to make notable inroads in the market. Moreover, based on the information collected in the investigation it appears[105] that SGWs are labour intensive to produce and require a very specialist procedure for their manufacture (under microscope); skilled manufacture which may require specialist personnel or at the least the ability to hire such people quickly. It is therefore all the more doubtful that any of the existing competitors or a new entrant could constitute a sufficiently serious and timely competitive threat such as to deter significantly the merged entity from raising prices.

(d) Conclusion

196. The concentration enables the merging parties to strengthen Guidant's uncontested leadership, by removing one of the only two main competitors in this market. On the basis of the information at the Commission's disposal, it seems unlikely that remaining competitors and potential entrants can constitute a sufficient and timely competitive

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[103] Papworth Hospital, folio 5928

[104] Boston Scientific reply to phase I IC questionnaire

[105] See Medtronic reply to the phase I questionnaire to competitors dated 16.03.05.

constraint such as to prevent a unilateral increase in prices by the merged entity. Further, it cannot be excluded that 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 may provide them the opportunity to attain higher prices than would otherwise have been the case. The merger is therefore likely to result in a significant impediment to effective competition in the common market and the EEA for steerable guidewires as a result of the strengthening of Guidant's dominant position.

B. ENDOVASCULAR DEVICES

1) The parties activities

197. J&J is active in the endovascular business through one unit of Cordis ("Cordis Endovascular"). J&J supplies the following endovascular devices in Europe: (i) stents, (ii) PTA balloon catheters, (iii) guiding catheters, (iv) diagnostic catheters, (v) catheter sheath introducers, (vi) steerable guidewires, (vii) diagnostic guidewires, (viii) embolic protection devices, (ix) venous products, (x) thrombectomy systems, (xi) AAA stent graft systems and (xii) accessories.

198. Cordis Endovascular had worldwide sales of € […]* million in 2003, around two-thirds of which was generated in the United States. Cordis Endovascular's EEA sales amounted to € […]* million.

199. Guidant produces and sells a more limited line of endovascular products. Its EEA business comprises: (i) stents, (ii) PTA balloon catheters, (iii) guiding catheters, (iv) steerable guidewires, and (v) embolic protection devices.

200. Guidant's worldwide sales of endovascular devices amounted to € […]* million in 2003, of which around […%]* or € […]* million was generated in the EEA.

2) The features of the markets

(a) Growth and innovation

201. The market for endovascular devices in Europe shows some features resembling those of the Interventional Cardiology area, although there are also notable differences. According to the Millennium report on European markets for peripheral vascular devices, dated April 2004, the total market for peripheral vascular devices, including stents and accessories was worth in 2003 around € 300 million in the four main European markets (i.e. France, Germany, Italy and UK)[106]. The report forecasts a moderately positive growth over the 2004-08 period, with a CAGR of 5.9% in value and 0.1% in the number of procedures. Within this area, two of the most dynamic segments are forecast to be that of endovascular stents, with a CAGR of 5.3% in value over the 2004-08 period and 7.8% in volume (8.7% for renal procedures, 15.8% for carotid procedures, and 11.5% for femoral and popliteal procedures) and that of Embolic

[106] See the report '*European Markets for Peripheral Vascular Devices*', Millennium Research Group, April 2004. The figure includes also peripheral vascular markets that are not affected by the concentration (e.g. surgical grafts, vascular closure devices). The parties' estimation of the size of the affected markets in 2004 is of € […]* million for the entire EEA.

Protection Devices, with a CAGR of 17.9% in value and 19.6% in volume over the 2004-08 period.

202. However, while it is true that the market growth will open new opportunities for new entrants and smaller players, the main driver of this growth is expected to be the increased penetration rate of endovascular procedures for the treatment of peripheral artery disease rather than breakthroughs capable of disrupting the current market dynamics[107].

203. In this process, the critical factor will be the ability of medical devices suppliers to convince physicians of the advantages of, for example, carotid stenting over carotid endarterectomy (the surgical treatment of carotid artery disease) through the production and dissemination of compelling clinical data and other information material, a capillary activity of teaching novel techniques and a constant activity of commercial product promotion.

204. Innovation appears to play a more modest role in the markets for endovascular devices than in the market for interventional cardiology devices. In particular, DES are not expected to become a pervasive device before the next three to five years[108] and certainly they will not develop to the same extent as they have done in the field of interventional cardiology. Some physicians expect the development of DES in the treatment of superficial femoral arteries but do not foresee a more widespread use (more dedicated to smaller arteries). For instance, the Millennium report gives the example of stents indicated for iliac procedure that are characterised by less innovation and where "*product differentiation begins to erode*", thus competition among suppliers is based on "*price, relationships and brand loyalty*"[109].

205. One possible explanation for the lower pace of innovation in endovascular as compared with interventional cardiology is related to the overall smaller size of the endovascular market. Additionally, peripheral procedures are not as homogeneous as for interventional cardiology. Therefore, demand is more diversified and the expected return from investments in innovation lower. There are new innovative devices on the market every year but the market suffers from its diversity compared to coronary arteries and the endovascular devices available are far more numerous.

206. That said, innovation remains one of the drivers of the market[110]. Among possible breakthrough innovations, the market investigation has indicated that some research and

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[107] Other factors, albeit less important from a purely quantitative point of view, are increased incidence of peripheral artery disease due to population ageing and the use of endovascular techniques in previously untreated lesions.

[108] See Morgan Stanley's report "*Hospital supplies & Medical Technological*", dated 230/02/2005, page 65 "*Despite these issues, based on recent clinician feedback it appears that drug-eluting peripheral stents could eventually be viable, probably near the end of the decade.*" [Emphasis added] "*That said, we think additional clinical data supporting this therapy will be needed before this technology becomes fully adopted by clinicians.*" […]*

[109] See the report "*European Markets for Peripheral Vascular Devices"*, Millennium Research Group, April 2004:

[110] See the report "*European Markets for Peripheral Vascular Devices"*, Millennium Research Group, April 2004: "*The introduction of new and improved balloon-expandable and self-expandable stents will continue to generate PV stent revenue until peripheral DES are approved. Incremental product improvements […] will continue to drive the overall market and support stenting in the peripheral.*"

development on bioabsorbable stents are underway, within the same time frame as for DES[111]. However, to the Commission's knowledge none of those projects are likely to radically change the market in the short to medium run, in particular for the purpose of the competitive assessment for endovascular applications.

(b) Entry barriers

207. As in interventional cardiology, the endovascular area is characterised by a number of significant entry barriers.

(1) Performance and clinical evidence

208. Firstly, the key to the success in this area is the performance of the devices, whose reliability needs to be proved by lengthy and costly clinical trials. Moreover, a recent important trend in the endovascular stent markets is towards an increased product specialisation via ad hoc clinical trials. While in the past the same endovascular stents (of course, with varying sizes) were used by physicians to treat different types of lesions (e.g. BX stents in renal and iliac procedures), there is in the medical community increasing awareness that stents with specific characteristics in terms e.g. of profile, radial force, deliverability, are better suited to treat specific types of lesions.

209. The specialisation and differentiation of stents is clearly linked to the size of the markets they will serve: the costs associated with the research and development, clinical trials and marketing of a new dedicated stent are very high, and such effort can be undertaken only if the target market is sufficiently large to offer an acceptable return on the investment. At the same time, the specialisation process increases the financial and human resource investment necessary to offer a complete line of products.

(2) Quality reputation and customer loyalty

210. Secondly, a supplier needs to build a strong relationship with the customer and brand reputation. As outlined above, competition in the markets for endovascular stents takes place more at the level of quality. In that regard, the merging parties contend that there is no real loyalty from the customers and thus the new entity will not benefit from any shifting of Guidant's market positions in favour of J&J. However, the market investigation provides some evidence that Guidant enjoys a sound reputation and has a well-perceived quality image. Out of 39 replies received from customers of endovascular medical devices to the market inquiry, 31 expressed their good perception towards Guidant, namely approximately 80%[112].

211. This good reputation is mainly based on the quality of Guidant's products (25% of the customers who replied to the questionnaire even considered Guidant to be a quality leader), but also on an experienced peripheral direct sales force, and an outstanding after-sales service, that enables physicians to attend training sessions. Moreover, this perception is valid across its product range[113]. The mere fact that J&J has announced

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111 See replies to question 49 of the questionnaire to customers.

112 See the replies to question 50 of the Commission's Article 11 letter dated 16/03/05 addressed to customers of endovascular devices.

113 See response from HEGP Paris (folio 6085) Question 36 "*Reputation is an element of choice and may compensate a moderate different price*"; response from Campus Sint-Jan (folio 6218) Question 24 "*quality*

that it will operate its global cardiovascular business under the brand name Guidant is a strong sign that it believes in the strength of this brand[114].

212. Moreover, competitors unanimously acknowledge the very sound reputation of Guidant among customers[115]. According to the rival suppliers of endovascular medical devices, this reputation has been earned through the quality of its products, by being very innovative, and investing in sophisticated training programmes for physicians, thus building historical relationships with them.

213. Loyalty is even more relevant when focusing on the carotid stenting procedure. Indeed, as explained above, carotid angioplasty is a complex procedure, with potential life-threatening consequences. As errors can be fatal, physicians are more reluctant to switch between brands unless there is very clear evidence of clinical superiority.

(3) Dedicated sales forces and geographic coverage

214. Thirdly, suppliers need to establish dedicated sales forces and secure a widespread presence on the territory. The market investigation stressed that a local presence is considered to be a determinant feature in being a credible supplier[116].

215. The parties retort that expansion and repositioning in neighbouring markets, especially for firms active in one or more endovascular segments or firms seeking to enter from similar cardiovascular product segments, would be relatively easy.

216. When looking at the cost of entry in domestic markets, different scenarios must be distinguished, depending on whether the new entrant intends to expand its product range in a geographical market where it is already present, is an existing player with no presence in a specific geographical market, or is an existing player that wants to enter a new product market or an entirely new player in the endovascular area.

217. In the case of a company that is already present in a specific national market and wants to expand its range by adding a product it already sells in other markets, barriers to entry are indeed low. Competitors with an established business in peripheral stents and accessories acknowledge that they would not face significant problems for launching an

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of the product comes at the first place! If a product has no specific reimbursement, we look for a package deal." And question 50 "*Guidant is quality leader for most of its products.*"; see Ziekenhuis Oost-Limburg (folio 6137) question 52 "*Guidant only went for high quality products. If it wasn't a high quality product, it wasn't to be developed. Hopefully, this will continue after the merger*.", see CHU Nancy (folio 6000) question 50 "*excellent perception. Portfolio very complete and very good quality. Innovative*.", see Service de Cardiologie du Nord (folio 6076) question 50 "*It seems to me that Guidant is perceived as a leader in terms of product quality.*", see Krankenhaus der Stadt Wien Rudolfsstiftung (folio 6073) "*Guidant good quality of products, very good support. A little higher price would be justified, but prices of the products are not higher.* and Question 50 *"Guidant is quality leader across its product range with competitive prices*."

114 […]*.

115 "*Guidant has a strong customer loyalty […]",* see EV3's response to question 19 of the Commission's Article 11 letter dated 04/05/05 addressed to competitors within the endovascular devices sector. "*Bard considers that Guidant has successfully established a very good reputation and well respected brand"* see Bard's response to question 19 of the Commission's Article 11 letter dated 04/05/05 addressed to competitors within the endovascular devices sector

116 See responses to question 23 of the Commission's Article 11 letter dated 16/03/05 addressed to customers of endovascular devices.

accessory lacking in their portfolio. This is because the sales, services and support functions would already exist and there would already be an existing customer base. However, this case represents the exception rather than the rule: suppliers who have a product available and an established sales organisation in a given country, do sell the product in that country[117].

218. Initial costs include training of the local existing sales force, production of marketing material in the relevant language, if necessary organisation of promotion events and training of physicians. For some countries (for example in Spain, Italy and France), entry costs are higher because they require additional product registrations on top of the normal registration process, namely CE certification, together with national labelling/packaging requirements which inevitably slow down the market entry. As for the capacity of competitors to accommodate increased demand, this depends on the capability to scale up production at short notice and on current capacity utilisation. The market inquiry revealed that some smaller competitors would face difficulties to accommodate an increased demand in a timely manner[118]. In the event of a sudden demand increase, not all competitors may be able promptly to scale up service functions such as order processing and distribution. Imports from other countries would also not be feasible as a short-term solution, due to re-labelling requirements imposed by Member States.

219. The costs associated with entry in a new geographical (national) market by a company present in other national markets are significantly higher. Although, according to the merging parties, investments and time required would be modest for an established supplier, their best estimates amount to approximately €2.5 million and from nine months to one year for de novo entry in a large EEA country. For smaller EEA countries, the costs are estimated to be around €900.000, with six to nine month period[119]. As an illustration, the parties submitted recent de novo entries of Guidant when it established de novo sales forces in two European countries for several business lines. […]. It should be noted that for those two particular de novo entries, Guidant relied upon an existing presence through independent distributors that were selling its line of medical devices, thus it hired its direct sales force from sales representatives from the independent distributors who had previously been handling sales of Guidant's products. Moreover, awareness of customers to Guidant's products already existed.

220. The market investigation revealed similar figures to the parties for entering a national market from scratch for an Endovascular business line only (from €1m to several million)[120]. However, competitors stressed that such entry would entail risks, in particular credibility and acceptance challenges. Within the total investment, relatively large sunk costs would be required whilst such entry could only be economically

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117 Short term differences in product lines may be observed at the time of launch of a new product, if the supplier chooses to phase it in gradually in different geographical markets.

118 See response of Bard with folio number 9019 dated 23/05/05 to the Commission's Article 11 letter dated 06/05/05 (question 14) "*Bard considers that the time required to meet substantial unanticipated demand would vary from 2 to 6 months. […] The other key consideration, in the event of a sudden demand increase, is available capacity in relation to service functions, such as order processing and distribution.*"

119 See memorandum with annexes from Johnson&Johnson with folio 10241 dated 06/06/2005, containing the parties' response to questions 12 and 13 contained in the Commission's information request dated 17/05/2005.

120 The competitors gave the figures on a confidential basis.

realistic if a reasonable market share could be reached, taking into account the total value of the country. Entry would obviously be more difficult for a company supplying a limited product range compared to one with a full line portfolio.

221. When looking at the investments to bear, the market enquiry listed several hurdles. Firstly, establishing a new direct sales force, the key determinant of market success, would require the recruitment of sales people (marketing/sales manager and sales person). Sales representatives in the vascular business are the main point of contact between the suppliers and the physicians: their role is not only to introduce the products in the operating theatre, but also to disseminate the results of scientific studies and clinical trials and to be able to respond to requests of assistance from the doctors. Sales representatives have often worked within the hospital (as specialised nurses, for example) before joining a supplier's sales force[121]. Secondly, even with the set up of a direct sales force, competitors stressed the importance to build relationships with customers to compete with well-entrenched large players and break through customer loyalty[122]. However, such effort is time-consuming and therefore explains that *de novo* entry cannot be timely. Thirdly, competitors have explained that the existence of long-term tenders has for consequence to "*lock-on the market for established companies*",[123] in particular for countries where tenders are generally more than two years, as for example Italy[124]. Additionally, purchasing through tenders or large direct negotiations may also require supply of a wide range of products. Fourthly, a certain expertise is required in order to adapt to local procedures, for registration and/or for reimbursement filings. Complementary scientific publications evidencing clinical effectiveness could also be required at this stage. Fifthly, medical devices suppliers have the obligation to translate into local language of the country concerned the "instructions for use", moreover, to ensure effective communication, marketing promotional materials are also translated. Finally, and not the least, training and education of customers, including participation to local events, constitute substantial necessary investments, that are key factors for a successful entry.

222. Perhaps more important than costs, timely entrance is an essential element for success. The market investigation sets that in the best case scenario, entry could be possible within a period of time around 15 months[125]. However, some competitors underlined that the process could take longer and that a realistic timeframe could involve two years or

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121 See response of Bard with folio number 9019 dated 23/05/05 to the Commission's Article 11 letter dated 06/05/05 (question 11) "*Sales force competency is a key determinant of market success.[…]This is very important because physicians expect sales representatives to have extensive procedural knowledge and be able to discuss both procedural and clinical issues with them.*', see also response of Edwards with folio number 9057 dated 23/05/05 to the Commission's Article 11 letter dated 06/05/05 (question 10) "*A large sales force with extensive coverage is also a key factor for success*."

122 See response of Bard with folio number 9019 dated 23/05/05 to the Commission's Article 11 letter dated 06/05/05 (question 11).

123 See response of EV3 with folio number 8675 dated 18/05/05 to the Commission's Article 11 letter dated 06/05/05 (question 10).

124 See response of Medtronic with folio number 8806 dated 19/05/05 to the Commission's Article 11 letter dated 06/05/05 (question 10).

125 See, as an illustration, response of Bard with folio number 9019 dated 23/05/05 to the Commission's Article 11 letter dated 06/05/05 (question 12).

more[126]. Obviously, such period may substantially be increased due to only one of the obstacles described above. The accumulation of these obstacles may even lead to preclude entry into a specific country[127].

223. These costs have to be examined in relation to the size of the relevant markets: a potential entrant decides to undertake initial entry costs on the condition that they can be recouped over an acceptable period of time. The likelihood that this is the case is directly proportional to the size of the market and to the market share that a new entrant is likely to achieve within that timeframe. Taking these factors into account, it is easy to see that initial entry costs can act as a deterrent to entry in a new national market, in particular when looking at sunk costs.

224. As a way of illustration, take Germany, by far the largest market in the EEA. According to the figures provided by the parties, the combined value of the stents, EPD and accessories markets was worth € [60-70]* million in 2004. Assuming an annual 6% growth rate (in line with the forecast in the Millennium report), that the new entrant has a full product range available, that the investment should be recouped over a period of three years –which roughly corresponds to the life-cycle of a vascular stent -, and that over this time frame it can hope to achieve a 5% market share (it should be borne in mind that the new entrant has neither established reputation nor commercial relations in the market), the German prospective turnover would be in the area of € [10-15]* million over three years (2005-07). This turnover may be sufficient to generate sufficient profits to cover an initial investment that the parties quantify in the area of € [0-5]* million. Under these optimistic assumptions, therefore, entry may be a possible response to an increase in prices.

225. However, the same may not be true if the new entrant does not have a full range of products. A new entrant offering BX stents (including both renal and iliac stents) and accessories could count on a German prospective turnover of around € [5-10]* million over three years. It cannot be taken for granted that this amount can sustain sufficient profits to justify the initial sunk costs associated with entry.

226. Looking at smaller countries, the case for entry becomes even less compelling. Using the same assumptions as above, a new entrant in the Netherlands would have a prospective market over three years of just over € [0-5]* million with a full range and of less than € [500,000 – 1,000,000]* with BX stents and accessories. In Belgium, the figures would be just over € [0-5]* million and € [0-5]* million respectively, in Spain around € [0-5]* million and € [0-5]* million respectively, in Austria below € [0-5]* million and over € [0-5]* million respectively. Even a major market as Italy may not have a market large enough to sustain entry (prospective endovascular market of € [5-10] million over three years for a company with a full range and of € [0-5]* million for a company with BX stents and accessories).

227. From the analysis above it results that entry in new geographic national markets cannot be assumed as the parties propose, even by a competitor already active in a

[126] See response of EV3 with folio number 8675 dated 18/05/05 to the Commission's Article 11 letter dated 06/05/05 (question 12) and response from Medtronic, with folio number 8806 dated 19/05/05 to the Commission's Article 11 letter dated 06/05/05 (question 12).

[127] See anonymous response with folio number 9669 dated 31/05/005 to a request for complementary information "*France: 2nd biggest market in EU which we attempt to approach since 2003*"

neighbouring market. The decision on whether to enter depends on a number of factors, among which the most important are: the size of the market, the initial fixed costs of entry, the range of products already available to the new entrant, the market share that could be captured within a reasonable timeframe.

228. The parties acknowledge that size of local demand and ability to recoup investment impact on the choice to set up a direct sales organisation, and add that whenever this route is not chosen new entrants can always rely on independent distributors at virtually no cost[128]. While it is true that this model reduces (but does not eliminate) entry costs, it also implies a much weaker presence on the market, with no direct contact with customers, reduced control on the marketing practices and therefore on key aspects of reputation building, and ultimately no possibility of acquiring a significant market share. It is a fact that, bar the smallest Member States (e.g. Slovenia, the Baltic States, Malta, Cyprus) no major player makes use of independent distributors. In all the most substantially affected markets the parties make use of direct sales forces. Only in Italy do the parties combine direct sales with agent sales and distributors[129]. The same is largely true for the parties' main competitors. It is therefore not credible that a new entrant in a national market that chooses to rely on independent distribution will be able to exert a sufficient competitive constraint on the incumbents.

229. The time and money costs associated with entry in a new product market or product segment (e.g. carotid stents, renal stents) by an existing player are also considerable: they include the costs associated with the design, development, clinical trials, approval procedures and marketing of the stent. This process is likely to take several years, and certainly more than two years. The parties estimate that regulatory approval for BX stents is obtainable within one year[130]. However, the time necessary is in all likelihood longer, especially considering that regulatory agencies are increasingly demanding regarding the specialisation, magnitude and quality of clinical trials in the endovascular area[131]. It is also to be stressed that regulatory approval is only one of the steps that needs to be accomplished to enter a new product market: the product needs first to be researched, developed and tested in vitro and/or in animals. Additionally, there is a time lag (that can range from several weeks to several months) between regulatory approval and market launch of the product.

230. From the above discussion, it is clear that entry in a new product market by players active in other product markets within the endovascular area cannot occur in a timely manner as a reaction, for example, to a small permanent increase in the price of the relevant product. Entry in a new product market is in all likelihood the result of a long term strategic choice of the new entrant, and follows a considerable investment in time and resources.

231. Finally, entry by an entirely new player in the endovascular area implies very high initial costs. Clearly, a new entrant would face all the costs detailed in the paragraphs above. Furthermore, the new entrant may have to acquire access to relevant patents or undertake additional investment in new designs. Some of the key patents are the same to

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128 See submission of the parties folio 10241 dated 6.6.2005, pp 4 and 5.

129 Luxembourg is often covered by the same sales representative as Belgium. See Annex 65 to the Form CO.

130 See submission of the parties folio 9632 dated 31.5.2005.

131 See the summary of conference call with Prof. Biamino, folio 11550 dated 17.6.2005.

those in the interventional cardiology area: e.g. those linked to the RX delivery system (relevant for renal stents) and stent design (relevant for BX stents); others are specific to the endovascular area[132]. Similarly to interventional cardiology, the importance of access to IP right is much more pronounced in the US than in EEA

232. More importantly, an entirely new entrant will need several years to develop a product line, gain acceptance as a credible and reliable competitor, and establish its presence on the market. It is clear that the threat new entry cannot offer a timely response to a small permanent increase in the price of endovascular products by the incumbents.

(4) Product range

233. Fourthly, the product range is an asset in this business. Suppliers indicated during the market investigation that having a broad product portfolio is a success factor in the peripheral business[133]. As illustrated above, a company with a full line of products and established reputation for service and product reliability[134], has the "critical mass" required to enable widespread local presence whereas a supplier with a narrower ranges may not be positioned to do the same and thus may have to rely upon third-party distribution. Moreover, a broad portfolio is an asset in negotiating package deals with the hospitals.

234. The market investigation has revealed that the leading suppliers, such as J&J, Guidant, Boston Scientific offer a wide product portfolio and are perceived by customers as a peripheral solution providers. Others, such as Bard, Medtronic, Abbott, offer a more limited range and concentrate only on some items.

235. Moreover, it should be noted that, unlike other competitors, following the merger the parties will have a strong position over the whole product range. Table H below list those countries in the EEA where the combined market shares for at least the BX stents are above a threshold of 40%, and the combined market shares for one or more accessories are around or above 40% and where there is a market share increase of at least 5%.

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132 See Form CO, pp. 362-366 and submission of the parties folio number 6047 dated 3003.2005. […]*.

133 See response of Bard with folio number 9019 dated 23.5.2005 to the Commission's Article 11 letter dated 6.5.2005 (question 17) "*[…]a broad portfolio supplier has a better chance of success than a single-product market entrant.*", see also response of EV3 with folio number 8675 dated 18.5.2005 to the Commission's Article 11 letter dated 6.5.2005 (question 17) "*Definitely a major asset for package deals and customer retention"*.

134 See below more specifically on this point.

Table H

Member State	Carotid stent		BX stent		G.C.		S.G.W		PTA balloon		EPD	
	MS	Δ	MS	Δ	MS	Δ	MS	Δ	MS	Δ	MS	Δ
Austria	[80-90]*%	2.048	[50-60]*%	1.610	[30-40]*%	450	[10-20]*%	60	[60-70]%	1.596	[30-40]%	580
Belgium	[50-60]*%	1.064	[70-80]*%	2.590	[70-80]*%	2.508	[10-20]*%	110	[40-50]%	594	[30-40]%	240
France	[30-40]*%	594	[60-70]*%	1.984	[80-90]*%	924	[10-20]*%	70	[30-40]%	448	[20-30]%	120
Germany	[50-60]*%	1.508	[70-80]*%	2.726	[40-50]*%	390	[0-10]*%	12	[40-50]%	420	[20-30]%	260
Italy	[40-50]*%	1.088	[60-70]*%	2.440	[30-40]*%	340	[20-30]*%	342	[30-40]%	450	[20-30]%	312
Luxembourg	[30-40]*%	352	[70-80]*%	2.464	[70-80]*%	1.220	[0-10]*%	40	[40-50]%	152	[10-20]%	72
Netherlands	[60-70]*%	2.160	[80-90]*%	3.078	[70-80]*%	1.152	[0-10]*%	12	[60-70]%	630	[10-20]%	78
Portugal	[80-90]*%	1.440	[80-90]*%	1.728	[60-70]*%	366	[10-20]*%	56	[40-50]%	92	[50-60]%	860
Spain	[50-60]*%	1.104	[60-70]*%	1.456	[80-90]*%	3.360	[0-10]*%	0	[20-30]%	156	[20-30]%	270

Source: Parties' data validated by the market investigation.

(c) Procurement and reimbursement

(1) General features

236. The demand is constituted by hospitals. Due to the national scope of the product markets, it is difficult to outline any general feature for the purchases and reimbursement of endovascular devices. Purchasing processes differ significantly between Member States, although there is a trend in some Member States towards a more widespread recourse to tenders in the procurement of endovascular devices. Additionally, many respondents to the Commission's market inquiry have indicated that they often tend to require package deals from their suppliers.

237. The parties claim that hospitals have strong countervailing buying power, in particular because they have several alternatives at their disposal and consequently they may play suppliers off against each other. Indeed, the parties have stressed that multiple sourcing is widespread across countries. The market investigation has confirmed that the great majority of buyers practice multiple sourcing.[135] In fact, there are very infrequent problems of interoperability between products sourced from alternative suppliers136. Multiple sourcing allows the hospitals to obtain the best device for each medical application but also to avoid any disruption to their activity in case of a problem in the supply of a specific device. The companies present in the supply of endovascular devices confirmed that customers who source from their own company do not source their entire requirements from them.

135 See responses to question 31 of the Commission's Article 11 letter dated 16/03/05 addressed to customers of endovascular devices.

136 See responses to question 32 of the Commission's Article 11 letter dated 16/03/05 addressed to customers of endovascular devices.

238. However, multiple sourcing does not necessarily translate in the absence of competition concerns. Customers can source from multiple suppliers as long as there is a sufficient number of them to choose from. Moreover, demand is highly fragmented relatively to the size and concentration of suppliers.

239. In their reply to the Statement of Objections, the parties have also argued that price is the key determinant of customers' choice in this field, and that Commission has not adequately investigated with customers the issue of whether the merger would give rise to a price increase.

240. The evidence in the file does not support this claim. The Commission's market inquiry has indicated that quality of the products is the most important factor in the selection of suppliers, followed by compliance with the technical requirements and physician's choice. Price is ranked only fourth in terms of importance, as is indicated in Table I below.

Table I

	Technical standards	Quality	Price	Training	After-sale support	Known supplier	Physician's choice	Range	Inter operability
Average vote	8.82	9.47	7.51	6.50	6.87	5.68	7.64	6.11	7.11
Number of responses	38	38	37	38	38	38	36	37	37

Source: market investigation. Votes where given from 1 (not important) to 10 (very important).

241. The relatively low weight given to prices in the choice of supplier reflects the specificities of procurement in the medical devices markets, where often the persons with the best knowledge that act as decision makers (i.e. the doctors) are not those in charge with financial matters related to purchasing (i.e. the hospital administration). For this reason, while pricing issues can be very important in determining availability of a specific type of devices to the decision makers (for example, in terms of reimbursement by the health authorities), they are not among the principal factors considered in the choice of a specific device.

242. From this it follows that competition in the markets for endovascular stents takes place more at the level of quality and acceptance by the physicians that act as decision makers within the hospitals than at the level of undercutting competitors' price. Issues as closeness of substitution and brand loyalty are therefore central to the analysis.

(2) Features of the most impacted countries

(i) **Austria**

243. In Austria, the reimbursement of medical devices is based on a modified diagnosis related groups system ("DRG")[137] according to which payments are based on flat per-case fees, which allows billing on the basis of actual services rendered by the fund hospitals. A nationwide uniform number of points is allocated to diagnosis-related groups and the points are transformed in monetary values for the purposes of

[137] Under a DRG system, patients are classified in diagnoses classes that group together patients with similar diseases, needs for treatment, lengths of stay and resource for billing purposes. The patient's actual diagnosis is converted into a DRG that is used to calculate the hospital's reimbursement.

reimbursement. Monetary values of the points can vary between federal states and hospitals, depending chiefly on budgetary considerations.

244. Procurement is usually carried out through direct negotiations between hospitals and suppliers, and formal tenders are very rare (between 0% and 10% of total volume). According to the parties, package deals are also rare ([…]* of total volume); however, smaller competitors have provided different estimates, indicating that package deals account from 20% to 50% of all sales[138].

(ii) **Belgium**

245. The National Institute for Health and Disability Insurance (INAMI/RIZIV) is the key decision maker when it comes to reimbursement of medical devices. All medical procedures and devices are reimbursed on the basis of a national list. INAMI/RIZIV decides which new devices are to be admitted for reimbursement and the level of reimbursement for devices already on the list. Reimbursement levels are obtained by class of products and type of procedure. The process to obtain reimbursement by INAMI/RIZIV has not fixed maximum duration. It may take up to two years. To date, renal and carotid artery stenting are not reimbursed.

246. There is a general consensus that there is no formal tendering in Belgium, or very seldom (between 0% and 10% of total volume). Most sales go via direct negotiation with the purchaser. It is worth noting that package deals are more frequent in Belgium, in particular for Guidant ([…]*% of endovascular sales within the country), to a lesser extent for J&J (between […]*% and […]*%). Such characteristic is confirmed by the market investigation that gives a range from 10% to 60% for package deals of all sales[139].

(iii) **France**

247. In France a DRG-type system was put in place on March 1st, 2005, and is expected to be fully operative in private hospitals by the end of this year and will be phased into public hospitals over the next seven to eight years. Most medical devices are included in the lump-sum reimbursed for medical procedures. A limited number of devices, such as DES, are funded separately (supplementary payments). Registration on the LPPR (Liste des Produits et des Prestations Remboursables) is however a prerequisite for inclusion on the list of supplementary payments. Application for listing on LPPR requires several simultaneous applications to the Ministry of Health, to the secretariat of CEPP (Commission d'Evaluation des Produits et Prestations) and to the secretariat of CEPS (Comité Economique des Produits de Santé).

248. The CEPP gives its opinion (clinical and safety assessment) and sends this to the supplier. If the supplier agrees with the opinion, the document is sent to the Ministry of Health and to the CEPS. If there is a disagreement with the CEPP, there is the possibility for a hearing with CEPP, which can review its opinion. The CEPS and the Ministry of Health make the final decision whether or not to allow the reimbursement of certain products and procedures. In practice the process usually takes approximately 9-12

138 See non confidential summary of confidential responses by competitors, folio 11551 dated 17/06/05.

139 See non confidential summary of confidential responses by competitors, folio 11551 dated 17/06/05.

months. French Authorities do not recognize Carotid stenting as a first line therapy, and hence carotid stents are not reimbursed.

249. Tenders are commonly used in hospitals in France, it represents around 40-60% of endovascular device sales. This is particular true for public hospitals, where it is processed via formal sealed envelopes. Tenders are granted for one to two years[140]. In the private sector, negotiated deals are the usual practice. […]*. The competitors draw another landscape where package deals are more present, in a range from 30 to 60% of total endovascular device sales.

(iv) **Germany**

250. In Germany, a DRG system is mandatory from 1 January 2004. The DRG rates cover in principle the costs of medical devices and are reviewed yearly. All CE-marked medical devices used in hospitals and medical procedures performed at hospitals are in principle covered by the DRG system unless they are listed on a black list. However, coverage of endovascular devices is not yet completed, leading to limitation in the possibility to obtain reimbursement.

251. Procurement is usually carried out through direct negotiations between suppliers and hospitals or group purchasing organisation that represent a number of hospital and that can obtain better deals through high volume purchases. Formal tenders are very rare and according to most competitors cover 10% to 20% of total sales. Package deals are also rare ([…]* of total sales) according to the parties, while some competitors quote higher proportions (from 15% to 50%)[141].

(v) **Italy**

252. In Italy, a DRG system has been in place since 1995, although its coverage is not universal. Reimbursement rules vary considerably depending on the type of hospital involved (public, non-profit, private for-profit). Although there is a national list of DRG tariffs, reimbursement amounts can differ considerably between regions, which have the possibility to increment the amounts on a local basis.

253. Formal tenders account for the majority of sales of endovascular devices, with a percentage that ranges from 60% to 90% depending on the source. Tenders are usually long term, with supplier contracts often awarded for durations up to two or three years. The importance of package deals varies between 1% and 40%[142]. […]*.

(vi) **Luxembourg**

254. A device that has obtained a CE mark may be supplied in Luxembourg; no additional marks or labels are required. Each hospital operates an annual global budgeting system. The total budget is then allocated by department to cover their product/materials needs.

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140 See FormCo page 59.

141 See non confidential summary of confidential responses by competitors, folio 11551 dated 17.6.2005.

142 See non confidential summary of confidential responses by competitors, folio 11551 dated 17.6.2005.

255. Procurement in Luxembourg is effected by negotiated sales with physicians and the purchasing department or pharmacy. Most customers that have sufficient demand could be expected to conduct a competition for business should they see fit. For package deals, the parties provide the same estimates as for Belgium, the same goes for the competitors. This is particularly due to the fact that most of the suppliers rely upon the sales persons acting in Belgium.

(vii) **Netherlands**

256. In the Netherlands, the general funding is a mix of public health insurance and voluntary private insurance systems. For reimbursement, similarly to the situation in Luxembourg each hospital works via budgets by department. Product and general costs need to be managed within these budgets.

257. Formal tenders are very rare. Procurement of endovascular devices in the Netherlands is made via indicative tenders lists that are sent by the hospitals to the different companies. Each company can then propose their products and prices. Those lists are used as a starting point for private negotiations. As for package deals, the parties estimate that they represent around […]* of total sales, whilst competitors accentuate this figure to estimate it around 25%.

(viii)**Spain**

258. In Spain, reimbursement rules for medical devices are implemented independently at regional level. Some regions use a DRG system, while others have lists of approved products with maximum prices. It is expected that there will be an increasing adoption of a DRG-like funding system across regions, with an increasing impact of Health Technology Assessment on reimbursement decisions. Endovascular device products are usually fully covered under the Spanish reimbursement system.

259. The large majority of sales (80% to 90%) occur through formal tenders. According to the parties, package deals are infrequent (below […%]* for J&J and […%]* for Guidant); however, smaller competitors have provided different estimates, indicating that package deals account from 20% to 60% of all sales[143].

3) The competitive landscape

(a) Concentration of the supply

260. As to the competitive landscape, according to the merging parties, there is a vigorous competition, from a number of established players, across the different markets for endovascular devices. The parties mention several operators to support their claim: Abbott, Bard, Boston Scientific, B.Braun, Cook, Edwards Lifesciences, Ev3, Invatec, Medtronic, Sorin and Terumo, each competing with its respective strengths in some given product markets. Other local niche players are active in particular in the markets for endovascular accessories (guiding catheters, steerable guidewires, balloon catheters), where the barriers to entry appear to be lower.

[143] See non confidential summary of confidential responses by competitors, folio 11551 dated 17/06/05.

261. The investigation has provided a somehow different picture. Although there are a fair number of competitors in the endovascular markets, it should be noted that not all players have the same strength or are present in all product or geographic markets.

262. Importantly, notwithstanding the number of competitors operating at some level in Europe, concentration is high in many national markets. By way of illustration, Table J below sets out, for different stent markets, the combined 2004 market share of the top three and top four players in the most substantially affected markets[144]. It is possible to appreciate that the top three players have market shares that vary between 71% and 96%, depending on the country and on the product. Figures underlined indicate that *both* J&J and Guidant are among the top three or top four respectively. Figures in bold and underlined indicate that J&J and Guidant are the top two companies in the market.

Table J

	BX stents		Carotid stents		SX stents (non carotid)	
Member State	**Market shareC3**	**Market shareC4**	**Market shareC3**	**Market shareC4**	**Market shareC3**	**Market shareC4**
Austria	[70-80]*%	[80-90]*%	[90-100]*%	[90-100]*%	[90-100]*%	[90-100]*%
Belgium	[80-90]*%	[80-90]*%	[90-100]*%	[90-100]*%	[70-80]*%	[90-100]*%
France	[80-90]*%	[80-90]*%	[90-100]*%	n.a.	[80-90]*%	[80-90]*%
Germany	[80-90]*%	[90-100]*%	[80-90]*%	n.a.	[70-80]*%	[90-100]*%
Italy	[70-80]*%	n.a.	[80-90]*%	n.a.	[70-80]*%	[80-90]*%
Luxembourg	[80-90]*%	[80-90]*%	[70-80]*%	[80-90]*%	[80-90]*%	n.a.
Netherlands	[80-90]*%	[80-90]*%	[90-100]*%	n.a.	[70-80]*%	[80-90]*%
Portugal	[90-100]*%	[90-100]*%	[90-100]*%	n.a.	n.a.	n.a.
Spain	[80-90]*%	n.a.	[80-90]*%	[80-90]*%	[90-100]*	[90-100]*%

Source: Parties' data validated by the market investigation.. For BX stents market shares refer to value data, for carotid stents and non carotid SX stents to volume data, as no data in value was available to the parties. 'n.a.' means that it is not possible to identify the top three or four players (normally because the market share of one of the players is aggregated with that of other, smaller players).

263. The parties submit that some markets for endovascular devices are still at relatively early stages of development, and will experience fast growth rates in the future. For this reason, the parties doubt that past market shares can be used to predict market power of the combined entity and predict that market shares will fluctuate significantly as competition unfolds.

264. However, a general analysis of the suppliers' market shares of endovascular devices over the past three years (in which there has been significant growth of the market, starting from a low base) would rather reveal fairly stable market shares. According to the figures provided by the parties, J&J market share at EEA level (in value) in the

144 The threshold used in order to identify the most substantially affected markets is a) a combined market share above 40% and b) an increase of at least 5%.

market for BX stents was of [30-40]* in 2002 and [30-40%]* in 2003 and 2004; Guidant's was [25-35]*% in 2002, [25-35]*% in 2003 and [25-35]*% in 2004. A slightly different picture can be inferred from the volume data[145] on Carotid and Non-Carotid SX stents: while J&J's market share is stable (carotid stents: [15-25]*% in 2002, [15-25]*% in 2003, [20-30]*% in 2004; non carotid SX stents: [15-25]*% in 2002, [20 - 30]*% in 2003, [20-30]*% in 2004), Guidant, starting from a lower base, has increased significantly its market share (carotid stents: [15-25]*% in 2002, [20-30]% in 2003, [20 - 30]*% in 2004; non carotid SX stents: [0-10]*% in 2002, [0-10]*% in 2003, [10-20]*% in 2004). The data at EEA level is interesting because it shows that in the endovascular area there has been no event of product launch that is comparable in terms of market impact to the introduction of the Cypher DES first and Taxus DES after in interventional cardiology. The data at national level presents some more local variations than the aggregated EEA figures, as it is to be expected due to the smaller size of the markets. However there is no dramatic change in the market shares of the merging parties.

(b) Closeness of substitution

265. In highly differentiated markets as those for medical devices and for stents in particular, the choice of supply must also be weighted by the closeness of the available suppliers. In this respect, the market investigation has highlighted that the disappearance of Guidant as a competitor will eliminate the closest substitute to J&J stents. Tables K and L below summarise the results of the market investigation[146]:

Table K

	Purchase J&J product(s)	GDT 1st best alternative		GDT 2nd best alternative		GDT 1st or 2nd best
		Number	%	Number	%	%
endovascular stents in general[147]	11	4	36%	2	18%	55%
carotid stents	7	5	71%	2	29%	100%
BX stents	16	12	75%	2	13%	88%
of which renal	*2*	*2*	*100%*	*0*	*0%*	*100%*
SX stents (non carotid)	16	10	63%	2	13%	75%
Total	50	31	62%	8	16%	78%

Source: market investigation.

266. The majority (62%) of responses indicated that Guidant is the first best alternative to the products of J&J they purchase. In 78% of responses, Guidant is either the first or the second best alternative to J&J. It should be noted that this judgement is consistent across

145 No data in value was made available by the parties separately for carotid and non carotid SX stents.

146 See responses to question 45 of the Commission's Article 11 letter dated 16/03/05 addressed to customers of endovascular devices. Customers where asked to indicate the first and second next best alternative to the J&J and Guidant products they purchase. In some cases, the same customer mentioned more than one type of stent purchased from J&J or Guidant

147 This row summarises the responses of customers who did not name which particular product they purchase from the parties, but gave an indication on the first and second best alternative for endovascular stents in general. See responses to question 45 of the Commission's Article 11 letter dated 16.3.2005 addressed to customers of endovascular devices.

the different markets: Guidant's carotid stents are considered the best alternative to J&J's by five out of seven responses, the BX stents by 12 out of 16 and the non carotid SX stents by 10 out of 16.

Table L

	Purchase GDT product(s)	J&J 1st best alternative		J&J 2nd best alternative		J&J 1st or 2nd best
		Number	%	Number	%	%
Endovascular stents in general[148]	12	4	33%	0	0%	33%
carotid stents	13	5	38%	5	38%	77%
BX stents	25	16	64%	2	8%	72%
of which renal	*5*	*4*	*80%*	*0*	*0%*	*80%*
SX stents (non carotid)	18	11	61%	2	11%	72%
Total	68	36	53%	9	13%	66%

Source: market investigation

267. Similarly, the majority (52%) of responses indicated that J&J is the first best alternative to the products of Guidant they purchase. In 65% of responses, J&J is either the first best or the second best alternative to Guidant. Looking more closely at the specific markets under consideration, slightly fewer responses rate J&J the best alternative to Guidant than vice versa; J&J carotid stent are considered the best alternative to Guidant's by 5 out of 13 responses, the BX stents by 16 out of 25 and the non carotid SX stents by 11 out of 18.

268. The number of responses that indicated J&J and Guidant's competitors as next best alternatives are reported in Table M below for all types of endovascular stents):

Table M

	Purchase J&J products		Purchase GDT products	
	1st best alternative	2nd best alternative	1st best alternative	2nd best alternative
J&J			36	9
Guidant	31	8		
Boston Scientific	9	12	10	10
Bard	2	8	5	7
Medtronic	1	1	1	3
Cook	2	1	1	2
Terumo	1	1	2	2
Abbott	0	2	2	2
Other	4	6	9	10

Source: market investigation

269. The closeness of substitution between J&J and Guidant's endovascular stents is not matched by any other competitor in the market. Boston Scientific's products are

[148] See footnote above.

considered the next best alternative, but with a much lower number of indications. Bard is a distant fourth and other competitors are only occasionally mentioned. These findings are consistent across the whole range of products, with the sole exception of Guidant's carotid stent, for which more responses indicate Boston Scientific carotid stent as the first best alternative to Guidant.

270. To sum up, the market investigation has established that Guidant is by far the closest substitute to J&J endovascular stents. The reverse is also true, albeit to a lesser extent. This closeness of substitution undermines vigorously the alleged lack of competition concerns resulting from multiple-sourcing, as explained above.

271. In their reply to the Statement of Objections, the parties have claimed that the Commission's analysis of closeness of substitution lacks rigour. While not contesting the veracity of customer's statements, the parties challenged the conclusions reached by the Commission. According to the parties, the Commission should not have taken into account responses that mentioned company names (J&J, Guidant, etc) or specific type of products (renal stents, BX stents, SX stents) without mentioning the specific product names.

272. The Commission considers that it has taken in due account the information contained in the customers replies to its market investigation, and that it has reported it in a fair and accurate way. Regarding the answers that mentioned company names instead of specific products, these give an indication as to the closeness of substitution across the whole range of endovascular stents, which are the object of the Commission's analysis. As for the specific type of products, the subdivision is based on the product market definition used by the Commission, and not contested by the parties[149]. Significantly, the conclusion on closeness of substitution would not change if only the answer mentioning specific product names were to be taken into account: Guidant would still be the closest substitute to J&J endovascular stents, and vice versa[150].

4) Competitive assessment

(a) Endovascular Stents

(1) Balloon Expandable stents

(i) **The parties' activities**

273. Both parties supply BX stents in the EEA. J&J/Cordis BX stents for peripheral indications are sold under the Palmaz Genesis brand. Guidant's BX stents in the EEA are sold under the Omnilink and Herculink Plus brands. Both products are approved for all endovascular indications. The Herculink Plus, however, is mainly marketed as a stent for renal procedures.

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149 It should be noted that renal stents are presented in the analysis as a segment within the BX stent market and not as a separate market. In this segment, for example, Guidant's dedicated stent is in direct competition with a 'generic' BX stent from J&J.

150 Guidant is the first best alternative to J&J for 6 respondents out of 7 who mentioned specific product names in BX stents, and 4 out of 8 in SX stents. J&J is the first best alternative to Guidant for 5 out of 10 in BX stents, and 6 out of 11 in SX stents.

274. The total value of the BX market at EEA level is around € […] million in 2004. The parties estimate a volume of just over […]* stents sold in the EEA in 2004, or 37% of all endovascular stents. At EEA level, the combined market share of the merging parties amounts to [60-70]*[151] (J&J: [30-40%]*, Guidant: [25-35%]*). As indicated above those market shares have been relatively stable for the past four years. Already in 2001, the combined market share was of [60-70%]*, with J&J holding a more important position ([40-50%]*) while Guidant had a smaller market share at that time ([20-30%]*). After the transaction, the HHI will be 4,482, with an increment of 2,160.

275. When looking at the relevant geographic markets, i.e. each Member State, for the purpose of the competitive assessment, there are at least nine countries more substantially affected by the proposed merger in the BX stents market,[152] in a range from [50-60%]* to [80-90%]*. In the remaining Member States, the impact of the merger is relatively less substantial due to the small presence of both merging parties or to the absence of either J&J or Guidant: see Table N.

Table N

Member State	J&J	Guidant	Combined market share	Post HHI	Δ HHI
Austria	[20-30]*%	[30-40]*%	[50-60]*%	**3,875**	**1,610**
Belgium	[30-40]*%	[30-40]*%	[70-80]*%	**5,345**	**2,590**
France	[30-40]*%	[30-40]*%	[60-70]*%	**4,411**	**1,984**
Germany	[40-50]*%	[20-30]*%	[70-80]*%	**5,988**	**2,726**
Italy	[30-40]*%	[30-40]*%	[60-70]*%	**4,539**	**2,240**
Luxembourg	[20-30]*%	[40-50]*%	[70-80]*%	**5,458**	**2,464**
Netherlands	[50-60]*%	[20-30]*%	[80-90]*%	**6,924**	**3,078**
Portugal	[70-80]*%	[10-20]*%	[80-90]*%	**7,190**	**1,728**
Spain	[10-20]*%	[50-60]*%	[60-70]*%	**4,641**	**1,456**

Source: Parties' data validated by the market investigation.

(ii) **The impact of the concentration**

276. According to the notification, these combined market shares are not indicative of future unilateral market power that could significantly impede effective competition due to several reasons. First, there are a number of competitors that do not face output constraints. Barriers to entry or expansion are very low for endovascular BX stents, which are manufactured using the same tangible and intangible assets as coronary BMS. Secondly, the demand-side is characterized by a strong buying power with low switching costs to shift from one supplier to another. Thirdly, there is a significant degree of substitutability between SX and BX in the primary end-uses where BX stents are consumed and to some extent between BX stents and traditional surgical procedures.

277. Regarding the high number of competitors in the European BX stent market, the parties note that there are at least twelve suppliers with CE Mark approved BX stents[153].

151 All the market shares mentioned are extracted from the Form Co and based on value figures, unless otherwise stated.

152 The threshold used in order to identify the most substantially affected markets is a) a combined market share above 40% and b) an increase of at least 5%.

153 See submission of J&J with folio 9632 dated 31/05/05, pp 3 and 4.

However, the figures clearly show that only few companies account for the great majority of the market. As shown above, the top three companies account from 76% to 95%, and the top four from 88% to 98% of the markets in the most significantly affected countries. Importantly, J&J and Guidant occupy the top two positions in all these countries, with the sole exception of […]*, where Guidant is first, Boston Scientific second with a market of [10-20%]* and J&J third with [10-20%]*. Boston Scientific is the third most important player in all countries. The fourth player (usually Medtronic) never presents market shares in the double digits.

278. The above figures show clearly that the market in the countries under consideration is dominated by three companies, of which the two strongest are J&J and Guidant. Other players have only small or insignificant market shares, never over 10% according to the figures provided by the parties. In markets that are so concentrated, the competitive constraint that is exerted by other players is significantly reduced. Indeed, the responses of customers to the Commission market investigation have indicated that prices of BX stents have decreased moderately or have remained stable over the past three years[154]. This is in stark contrast to the price evolution of stents in the interventional cardiology area, where the price of BMS has plummeted due to the introduction of the DES and the fierce competition, and the price of DES decreased significantly after a second player (Boston Scientific) entered the market in 2003[155]. The fact that the merger combines the strongest and second strongest player and will create a dominant position in virtually all the markets considered will in all likelihood lead to a significant impediment to effective competition.

279. As argued above, barriers to entry can be significant in these markets, with the infrequent exception of a market player already established in the national market and that wishes to introduce a product that is already being sold in neighbouring markets. Additionally, the similarities between endovascular BX stents and BMS in interventional cardiology are limited to the basic design, use of material and delivery systems. Specific design, manufacturing, clinical trials, approval process, and for most players marketing and sales forces are clearly separated between the two product markets.

280. Furthermore, the fact that already numerous players are present in some or all the markets but do not succeed in gaining significant market shares in exerting a significant downwards pressure on prices indicates that entry by a small player is not sufficient to result in a competitive constraint that is as effective as having the two major players, J&J and Guidant, competing with each other.

281. Also the existence of countervailing buyer power and the practice of customer switching cannot be a sufficient factor mitigating the impediments to effective competition induced by the concentration. It is certainly true that hospitals practice multiple sourcing and stimulate competition among suppliers, as the Commission's market inquiry has established. However, the stents are highly differentiated products, which are evaluated by physicians according to a multidimensional scale. When a product is deemed very good or superior for the treatment of a specific lesion, only products with the same

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154 See responses to questions 14 and 16 of the Commission's Article 11 letter dated 16.3.2005 addressed to customers of endovascular devices.

155 See responses to questions 13 and 15 of the Commission's Article 11 letter dated 16.3.2005 addressed to customers of interventional cardiology devices.

characteristic or reputation are effective substitutes. Products with uncertain or insufficient medical properties or scarce acceptance among the medical community cannot be considered immediate substitutes.

282. As to the substitutability between BX stents and traditional surgical procedures, there is no evidence showing that a price increase in the price of stents would lead physicians to switch to surgery (allegedly, by deciding not to carry out the endovascular procedure and by referring the patient to a surgeon). It is true that the relatively high price of endovascular procedures compared to surgery limits the growth of the endovascular markets, but in this respect the decision of the public authorities to reimburse certain procedures and the education of doctors and patients in their use are the driving growth factors. Small, if permanent, changes in the price of endovascular devices would have only a very indirect impact on the switch towards minimally invasive endovascular procedures.

283. Similarly, the claim of a high degree of substitutability between BX and SX stents is not supported by the Commission market investigation. As it has already been illustrated in the section on market definitions, BX and SX stents form clearly separate markets. For most procedure (renal, SFA, carotid), physicians[156] have reported a clear preference for either BX or SX stents, which results in penetration rates close to 100%. Only in iliac procedures some degree of interchangeability has been noted. However, a detailed assessment of the answers reveals that while BX and SX stents can both be used in iliac procedures, only in very specific circumstances they can be used to treat the same section[157] and or the same type of lesion[158]. Using a type of stent that is not the most indicated for the target lesions may lead to significant adverse events for the patients (including stent fractures, restenosis, and the need for a repeat intervention); physicians would simply refuse to use an inferior solution following a price increase in the best choice product.

284. Even within the BX stents, there is growing evidence of a trend towards increased specialisation, product differentiation and reduced degree of substitution. Suppliers tend to design, test and market stents dedicated to specific application rather than conceived for general endovascular use, even if the stents receive CE Mark as generic endovascular stent[159]. Dedicated BX renal (e.g. Guidant's Herculink, Medtronic's Racer,

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156 See responses to questions 5 and 6 of the Commission's Article 11 letter dated 16/03/05 addressed to customers of endovascular devices, the summary of conference call with Prof. Cremonesi, folio 10116 dated 03/06/05 and the summary of conference call with Prof. Biamino, folio 11550 dated 17/06/05.

157 See the summary of conference call with Prof. Biamino, folio 11550 dated 17/06/05: "*In the pelvic area, BX stents use is limited to the area near the bifurcation of the aortic artery. On the external iliac section, SX stents are used.*"

158 As noted above, BX stents are preferred for more calcified lesions due to their higher strength in breaking the plaque that covers the arteries, while SX stents are favoured for placement in areas subject to contraction and torsion, thanks to their superior flexibility and capacity to return to their original shape.

159 See summary of conference call with Prof. Cremonesi, folio 10116 dated 03/06/05, "*A [...] trend can be seen for BX stents: while in the past there were very few dedicated stents, today there are stents that focus on renal or iliac-femoral applications. Clinical experience has shown that, while in the short term the results of different types of stents are comparable, stents designed for specific applications lead to better long term (e.g. after two years) results. It needs to be noted that this evaluation is not based on evidence based medicine (very few scientific studies have been conducted), but on the experience of practitioners and experts in the area.*"

Abbot's Jostent, Sorin's Radix and J&J's Palmaz Blue Renal[160]) and dedicated BX iliac stents (e.g. e.g. Guidant's Omnilink and Medtronic's Bridge Assurant) have different technical characteristics (that go beyond the range of sizes) that make them only very partially substitutable. Other BX stents, especially of older generations, are more difficult to classify.

285. The parties have provided indicative market shares on the BX stents used in renal applications (where Guidant is present with the Herculink stent and J/J is currently present with its Genesis stent)[161]. Due to the impossibility to know exactly which stents are used in renal versus iliac procedures, the parties have classified all BX stents with a diameter of less than 7 mm as renal stents. The resulting (indicative) market shares are slightly different to those for all BX stents, but confirm the very important horizontal overlaps between J&J and Guidant, as is illustrated by Table O below:

Table O

Member State	J&J	Guidant	Combined market share
Austria	20-25%	15-20%	**35-45%**
Belgium	25-30%	45-50%	**70-80%**
France	35-40%	40-45%	**75-85%**
Germany	25-30%	25-30%	**50-60%**
Italy	25-30%	25-30%	**50-60%**
Luxembourg	35-40%	20-25%	**55-65%**
Netherlands	60-65%	30-35%	**90-100%**
Portugal	80-85%	0%	**80-85%**
Spain	0-5%	35-40%	**35-45%**

Source: Information from the parties.

286. As described above, the merger will combine the leader and the number two[162] in the BX stent markets analysed above. The market investigation suggests that Guidant, is perceived as the best supplier in terms of quality products (in particular the stent delivery system), sales force and after sales service. This perception is shared across the industry by both customers and competitors. Guidant's penetration in the BX stents market for the past four years in every Member States seems to confirm these views. Some customers even acknowledged that they would be keen to pay a higher price for obtaining Guidant's products, including BX stents.

287. In conclusion, in the markets for BX stents in Austria, Belgium, France, Germany, Italy, Luxembourg, The Netherlands, Portugal and Spain, the concentration will result in the removal of the closest and strongest competitor to the market leader J&J. The merger will therefore significantly impede effective competition in the markets for BX stents in the above cited countries, in particular as a result of the creation of a dominant position.

160 See Form CO p. 351.

161 See submission of J&J folio 10241 dated 06/06/05, p.6.

162 […]*.

(2) Carotid stents

(i) **The parties' activities**

288. Both J&J and Guidant market carotid (SX) stents in the EEA. J&J markets its Precise SX stent principally for carotid indications, and Guidant markets its dedicated Acculink SX nitinol stent.

289. The parties have provided figures in volume for what regards the carotid stent market. The total value of the SX market at EEA level, including carotid and non carotid was over € […]* million in 2004, for a volume of over […]* units. Of these, just over […]* or […]*% were carotid stents. The proportion is higher in value, since carotid stents sell to a premium (around 15%) with respect to non carotid SX stents. The number of procedures is forecast to grow rapidly (according to Millennium, with a CAGR of 15.8% in the 2004-08 period), as carotid stenting gains wider acceptance as a less invasive alternative to the surgical procedure.

290. At EEA level, the combined entity had a merchant market share[163] of [45-55%]* in 2004 (J&J: [15-25%]*, Guidant: [20-30%]*). J&J's market share has been relatively stable for the past three years. Conversely, Guidant entered the market in 2000 and since then its market position has constantly grown to reach today [20-30%]* of the total EEA market. After the transaction, the HHI will be 3663, with an increment of 1176. In the remaining Member States, the impact of the merger is relatively less substantial due to the small presence of both merging parties or to the absence of either J&J or Guidant.

291. The Member States most substantially affected are those shown in Table P below:

Table P

Member State	J&J	Guidant	Combined market share	Post HHI	Δ HHI
Austria	[15-25]*%	[50-60]*%	[70-80]*%	**6.029**	**2.240**
Belgium	[10-20]*%	[30-40]*%	[45-55]*%	**4.375**	**1.064**
Finland	[65-75]*%	[10-20]*%	[85-95]*%	**8.362**	**2.628**
France	[5-15]*%	[20-30]*%	[35-45]*%	**4.739**	**638**
Germany	[20-30]*%	[20-30]*%	[45-55]*%	**3.712**	**1.296**
Italy	[10-20]*%	[20-30]*%	[40-50]*%	**3.675**	**1.008**
Netherlands	[15-25]*%	[30-40]*%	[55-65]*%	**4.695**	**1.716**
Portugal	[65-75]*%	[0-10]*%	[75-85]*%	**6.789**	**1.168**
Spain	[5-15]*%	[35-45]*%	[45-55]*%	**3.819**	**1.040**

Source: Parties' data validated by the market investigation. (based on volume)

(ii) **The impact of the concentration**

292. There are three main players in the carotid stent market: J&J, Guidant and Boston Scientific. Together they account for 83%[164] 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). It is important to note that, although other

[163] All the market shares mentioned are extracted from the Form Co and additions thereof and are based on volume figures, unless otherwise stated.

[164] [70-80%]* in the tiny Luxembourg market.

players (Abbott, Cook, ev3, Medtronic, Optimed) offer carotid stents and EPDs in Europe, their products have so far failed to gain wide acceptance.

293. The parties do not consider that the very high market shares of the top three market players are indicative of the competitive situation[165]. They point out firstly that new products to treat carotid artery disease have entered the market recently: Abbott's Xact in 2003, Cook's Zilver (this product is however approved in the US for biliary, not carotid, indications), ev3's Protégé in 2004, Medtronic's Exponent in 2004, OptiMed Sinus in 2004. Other are about to enter the market: Bard Conformexx, and Boston Scientific NexStent. […]*. On the market share front, the parties mention significant deals concluded in 2004 by new entrants in the fast growing German and Italian markets, as well as isolated, anecdotal evidence of further deals concluded in the first part of 2005. Finally, the parties provide statements of a number of US based physicians that do not consider that the merger between J&J and Guidant will have any negative competitive effects in the market for carotid stents, given the high number of potential entrants in the US carotid stent market[166].

294. The reason adduced by the parties to claim that the very high market shares of the combined entity in the carotid stent market are not indicative of the competitive landscape post merger are not convincing. Firstly, the entry of new products in the market between 2003 and 2004 has not lead to a decrease in the parties' market share: EEA wide J&J's market shares increased from [15-25%]* in 2003 to [15-25%]* in 2004; Guidants from [20-30%]* in 2003 to 28% in 2004. At national level, J&J market share increased in six of the nine most significantly affected markets[167] and Guidant in all nine.

295. The examples of Germany and Italy provided by the parties are emblematic.[…]*.

296. […]*.

297. The figures above show clearly that neither fast market growth nor new entry weakened the strong market presence of J&J and Guidant in the carotid stent markets. While it is true that not all new entrants were present on the markets in 2004, the figures indicate that the entry of a considerable number of new competitors (one in 2003 and further four in 2004) did not dent the parties' leadership positions.

298. […]*[168]. However, the sales data shows that J&J's carotid stent has maintained high and constant positions in fast growing markets and despite recent new entry; and the market investigation has indicated that Guidant Absolute is the first best alternative to J&J Precise[169], therefore constituting an important competitive constraint to it. J&J and Guidant's positions are reinforced by the considerable financial resources they are

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165 On these points, see submission of J&J with folio 8086 dated 04/05/05, pp 6-9.

166 See submission of J&J with folio 8086 dated 04/05/05, annexes 25-38. See also submission of the parties folio 10856 dated 10.06.05 for analysts reports looking at the competitive situation of the US carotid market.

167 Except Finland, Portugal and Spain.

168 See summary of conference call with Prof. Cremonesi, folio 10116 dated 03/06/05 and the summary of conference call with Prof. Biamino, folio 11550 dated 17/06/05.

169 See responses to question 45 of the Commission's Article 11 letter dated 16/03/05 addressed to customers of endovascular devices.

devoting to the teaching of carotid stenting techniques, thereby increasing their market recognition and brand reputation[170].

299. Additionally, […]* it must be noted that carotid stenting is undergoing a phase of incremental improvements to the stents, rather than of breakthrough innovation as it is the case for example for DES in the interventional cardiology area. The material of choice for carotid stents is nitinol, which is used by virtually all competitors[171]. A notable improvement is the development of tapered stents, which conform better to the shape certain anatomic situations in the carotid artery[172]. Acculink of Guidant already offers tapered stents and […]*.

300. Finally, the statements of US based physicians on the likely effects on the merger in the carotid area do not seem relevant for the assessment of the European situation. Indeed, it should be borne in mind that the market conditions in the United-States are very different. So far Guidant has currently the only FDA approved carotid stent, and thus enjoys a monopoly position in the market. J&J is one among a number of potential competitors in this market, and probably is not the most likely next entrant (which is likely to be Abbott).

301. To conclude, none of the factors that the parties indicate as invalidating the negative effects of the merger on the competitive situation in the markets for carotid stents has been proven to the requisite standard. Given the characteristics of the markets of carotid SX stents in Austria, Belgium, France, Finland, Germany, Italy, Luxembourg, The Netherlands, Portugal and Spain in terms of concentration, barriers to entry, customer loyalty, closeness of substitution, and as a result of the elimination of a major competitive constraint, 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.

(3) Non-Carotid stents

(i) **The parties' activities**

302. Both J&J and Guidant market non carotid SX stents in the EEA. J&J markets its SMART SX nitinol stent, and Guidant markets its Absolute SX nitinol stent. Non carotid SX stents are used principally for the treatment of arteriosclerosis femoral and popliteal arteries (also referred to "superficial femoral artery" or "SFA") and in the iliac arteries (most frequently in the external iliac section).

303. The parties have provided figures in volume for what regards the carotid stent market. The total value of the SX market at EEA level, including carotid and non carotid was

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170 See summary of conference call with Prof. Cremonesi, folio 10116 dated 03/06/05.

171 The only exception is Boston Scientific's WallStent. However its new product, the NexStent, is made of nitinol. For a description of various carotid stents, see "*Carotid Artery Stenting: State of the Art*"; Kasja Rabe and Horst Sievert, Journal of Interventional Cardiology, Vol. 17, No 6, 2004.

172 See summary of conference call with Prof. Biamino, folio 11550 dated 17/06/05. See also e.g.: "*Increased Efficacy of Internal Carotid Artery Stenting Using a Low-Profile Stent With a Tapered Tip*". Choragudi, Nagaraju; Pucillo, Anthony; Mateo, Romeo; Aronow, Wilbert; Botet, Jose; Cardiology in Review.13(1):24-26, January/February 2005.

over € […]* million in 2004, for a volume of over […]* units. Of these, over […]* or […%]*where non-carotid SX stents. The proportion is lower in value, since non carotid SX stents sell to a discount with respect to carotid stents. The market is forecast to experience rapid growth in the next years (according to Millennium, femoral-popliteal[173] procedures will have a CAGR of 11.5% in the 2004-08 period, with a corresponding increase in the volume of stents sold).

304. At EEA level, the combined entity had a merchant market share[174] of […%]* in 2004 (J&J: [20-30%]*, Guidant: [10-20%]*). J&J's market share has been relatively stable for the past three years. Conversely, Guidant entered the market in 2000 and since then its market position has constantly grown to reach today [10-20%]* of the total EEA market. After the transaction, the HHI will be 2691, with an increment of 600.

305. The Member States most substantially affected are those shown in Table Q:

Table Q

Member State	J&J	Guidant	Combined market share	Post HHI	ΔHHI
Austria	[30-40]*%	[30-40]*%	**[65-75]*%**	**5863**	**2736**
Belgium	[30-40]*%	[10-20]*%	**[45-55]*%**	**3562**	**1184**
Germany	[30-40]*%	[10-20]*%	**[40-50]*%**	**3100**	**900**
Netherlands	[40-50]*%	[0-10]*%	**[45-55]*%**	**3382**	**720**

Source: Parties' data validated by the market investigation.

(ii) **The impact of the concentration**

306. In three of the above markets, J&J is market leader, while it is number two in Austria. Guidant is the market leader in Austria, the third player in Belgium (after Bard) and the fourth in Germany and The Netherlands (after Boston Scientific and Bard). Together, J&J, Guidant, Boston Scientific and Bard account for [90-100%]* of the market in Austria, [85-95%]* in Belgium, [80-90%]* in Germany and [80-90]*% in The Netherlands. As illustrated above, the Commission market investigation has indicated that J&J and Guidant are considered the closest substitutes by the majority of respondents who specified non carotid SX products[175].

307. The parties have also provided indicative market shares on the non-carotid SX stents used in SFA applications[176]. Due to the impossibility to know exactly which stents are used in SFA versus iliac procedures, the parties have classified all non carotid SX stents with a diameter o less than 8 mm as SFA stents. The resulting (indicative) market shares

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[173] Femoral-popliteal or "fem-pop" procedures refer to procedures for treatment of the main arteries of the tights (femoral) and knees (popliteal), which constitute the great majority of the procedures in the legs. As explained above, the same procedures can also be referred to as "SFA" or "Superficial Femoral Artery" procedures. The term SFA is sometimes used for all procedures in the legs, including the arteries below the knee (tibial and peroneal). The latter procedures are still very rare compared to femoral and popliteal.

[174] All the market shares mentioned are extracted from the Form Co and additions thereof and are based on volume figures, unless otherwise stated.

[175] Guidant was considered J&J's closest substitute in 10 out of 16 responses of doctors purchasing J&J's non carotid SX stents. Similarly, J&J was considered Guidant's closest substitute in 11 out of 18 responses of doctors purchasing Guidant's non carotid SX stents.

[176] See submission of J&J with folio 10241 dated 6.6.2005, p.7.

are similar to those for all non carotid SX stents for Austria and Belgium and indicate a significantly more important horizontal overlap in Germany and The Netherlands, as is illustrated by Table R below:

Table R

Member State	J&J	Guidant	Combined market share
Austria	[25-35]* %	[45-55]* %	[75-85]* %
Belgium	[35-45]* %	[10-20]* %	[50-60]* %
Germany	[55-65]* %	[15-25]* %	[75-85]* %
Netherlands	[55-65]* %	[15-25]* %	[75-85]* %

Source: Information from the parties.

308. Furthermore, on SFA stents in particular, recent independent research has shown that important differences in terms of safety and efficacy exist between stents[177]. Within the sample of stents studied, Guidant's Absolute and J&J's Smart fared very well. According to this research[178], some products lead to relatively large amounts of fractures (over 37% in the studied sample). Fractures are associated with a higher in-stent restenosis and vessel reocclusion rate. It is one of the most important risk factors in SFA stenting and is currently the most important aspect of research for SFA stents.

309. The Smart stent presented a 15% fracture rate, that was well below the average (as a term of comparison, the Luminexx stent of Bard presented a 52% fracture rate, and SelfX of Abbott a 31% fracture rate), and very little restenosis (below 15% in long lesions averaging 18 cm). The fracture risk of the Absolute stent is lower than Smart's, however restenosis rates are relatively high[179].

310. The results of this independent research will in all likelihood enhance the perception that J&J and Guidant non carotid SX stents are very good products, and close substitutes due to their superior performance compared to competing stents.

311. In conclusion, given the characteristics of the markets of non carotid SX stents in Austria, Belgium, Germany and The Netherlands in terms of concentration, barriers to entry, customer loyalty, closeness of substitution, and as a result of the elimination of a major competitive constraint, the concentration will give rise to non coordinated adverse effects in those national markets and therefore impede effective competition in the

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177 In their reply to the SO, the parties, while not casting any doubts to the accuracy of the study, have noted that it cannot be taken as conclusive evidence. However, they have not provided any further elements to complement the analysis.

178 *"Prevalence and clinical impact of stent fractures after femoropopliteal stenting"*; Dierk Scheinert, Susanne Scheinert, Jacqueline Sax, Christopher Piorkowski, Sven Bräunlich, Matthias Ulrich, Giancarlo Biamino, Andrej Schmidt, Journal of the American Collage of Cardiology, Volume 45, issue 2, 18 January 2005. See also the outline of the presentation of D. Schneidert at 2004 Transcatheter Cardiovascular Therapeutics conferecence with title "Strut Fracture in Different Self-Expandable Nitinol Stents: A Prospective Analysis", folio 11555 dated 17.6.2005.

179 See summary of conference call with Prof. Cremonesi, folio 10116 dated 03/06/05 and summary of conference call with Prof. Biamino, folio 11550 dated 17/06/05.

common market and the EEA as a result of the creation or strengthening of a dominant position.

(4) Conclusion on endovascular stents

312. The concentration will reduce the number of most important competitors from three (the third being Boston Scientific) to two in the BX stents and carotid stents markets and from four (the third and fourth being Boston Scientific and Bard) to three in the non carotid SX stent market. These restricted number of players account for the lion's share of the market in all countries considered above. Further competitors, although numerous, have failed so far to grab significant market shares. The concentration will either consolidate an existing leadership position of one of the merging parties or create a new market leader.

313. The millennium report has listed the critical success factors in order for a company to compete successfully in the peripheral stent market. Those factors may undoubtedly be extended to the overall endovascular business. Firstly, and unsurprisingly, the key element is the performance of the devices, supported by good clinical data. In light of the respective market shares of the two companies, it is uncontroversial to claim that both supply high quality products, also having regard to the customers' statements during the market investigation.

314. Secondly, the report underlined that a strong relationships with customers and brand reputation are two additional critical success factors in this business. J&J and Guidant have both a very good reputation across their product range, vast financial and human resources capabilities to develop new products in a market space that is growing and fragmenting at the same time, an excellent reputation and commercial relation with their customers.[180] This is even more accurate for Guidant. Unanimously, customers and competitors acknowledge the outstanding reputation of Guidant's products. Reputation earned through the provision of good product design and quality, customer service, highly sophisticated educational programs and clinical support. The market inquiry indicated that this good reputation will be a important asset post-merger to entrench customer loyalty towards the merged entity's combined products and in particular to expand their sales to less successful product of the combined entity (Guidant name will remain on the market and thus substitute J&J (Cordis) brand name).

315. Finally, the report stressed that the offer of a full stent line enhances physician brand loyalty. The reasons for this line of argument are twofold: physicians that are satisfied to manipulate "*stent of high quality and easy to use are more likely to use products by the same company across indications*", but also the "*image of a company with gaps in its product line suffers as gaps signify an inability to recognize market needs*"[181]. EV3, in their first submission to the Commission, acknowledge that a "*full portfolio*" gives an

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180 See Morgan Stanley's report "*Hospital supplies & Medical Technological*", dated 23/02/05, page 60 "*J&J's Cordis division remains a leader in peripheral market in our view. We think that one of the drivers is the wealth of marketing and financial resources the company has as its disposal, which enables it to market to various customers including interventional radiologists, interventional cardiologists and vascular surgeons. […] As the peripheral market continues to grow, we believe that J&J should remain a market leader and is well positioned to benefit from his growth.*"

181 See the report "*European Markets for Peripheral Vascular Devices"*, Millennium Research Group, April 2004, page 121.

advantage to Guidant, J&J and Boston Scientific, whilst in the same time it is a weakness for companies such as Medtronic and Abbott[182]. The same argument has been put forward by Medtronic, indeed they consider that a full product portfolio gives a "*competitive edge*" and a supplier with such advantage is "*perceived by customer as a peripheral solution provider rather than a peripheral stent provider*"[183].

316. The relevant product markets are characterised by differentiated products. The market inquiry established, particularly on the basis of a customer preference survey that overall J&J' products are closer substitutes to Guidant's products than others. Where J&J products are purchased by a hospital, Guidant is generally considered to be the closest substitute. The reverse relation (J&J products considered the closest substitutes to Guidant's) is also true, although to a lesser extent. Importantly, this closeness of substitution is not matched by any other competitor. Finally, the combined portfolio of products of the combined entity will in all likelihood enhanced its strong position across the products.

317. The parties have argued that any unilateral action, such as price increase, by the merging parties can be undermined by the competitors, chiefly because barriers to entry are low both at the industry level and at the level of specific markets. They have also argued that past performance is not a good predictor of the future competitive landscape, because the markets are growing rapidly and new entry is occurring. Finally, in their reply to the Statement of Objections, the parties have claimed that the customers responses to the Commission investigation prove that there are no concerns related to the merger, because only around 25% of the interviewees replied to the questionnaire, and of this only 30% expressed concerns.

318. The Commission's investigation has not, however, confirmed these claims. There are considerable barriers to entry, in the form of IP rights, know how, access to customers and reputation that make entry in the industry difficult. Entry in a new national market from scratch would require a substantial financial investment (from €1m to several million) in order *inter alia* to establish a new sales force, training and education of customers, participation of local events that are key determinants of market success and from one to two years. Therefore, such entry would entail risks, in particular credibility and acceptance challenges, and large sunk costs whilst it could only be economically realistic if a reasonable market share could be reached, taking into account the total value of the country. Such entry would obviously be more difficult for a company supplying a limited product range compared to one with a full line portfolio.

319. Therefore, entry cannot be seen as a possible reaction to, e.g. a small but permanent increase in prices. Entry is determined by strategic decision of the competitors that are taken looking at long term market trends rather than short medium term price fluctuations.

320. Furthermore, competition in these markets takes place at the level of quality of the product and acceptance by the medical community. Doctors do not switch from their product of choice following a small price increase, unless they are confident that the

[182] See response of EV3 with folio number 6264 dated 01/04/05, question 37.

[183] See response of Medtronic with folio 8806, dated 19/05/05, question 17.

alternative product is a close substitute and at least as efficacious as their product of choice.

321. As for the impact of market growth and entry on the competitive landscape, available data shows that they have not impacted negatively on the parties' market shares. On the contrary, the parties have been able to match or outperform the growth in the size of the market. They are also best place to take advantage of the specialisation process that is taking place in the stent markets through the offer of a complete and differentiated portfolio of products.

322. Finally, the Commission does not consider that a low rate of response to its questionnaire can be construed as meaning that the merger will not pose competition concerns. Firstly, it is particularly difficult to reach the customers in the health related markets, because the demand is not clearly identified (e.g. physicians to a large extent choose the devices they use, but often are only marginally aware of their cost) and does not act in a commercial manner. Secondly, a number of customers could not be reached or could not answer the questionnaire because of lack of knowledge of the field. Thirdly, the parties base their claim on the answers to one specific open question[184] that the great majority of respondents left blank. The Commission, on the other hand, has based its analysis of the wealth of information (such as on closeness of substitution, perception of competitors, etc.) contained in the replies to all questions posed.

323. In view of these elements, there is sufficient evidence showing with the requisite degree of confidence that the operation will give rise to important non-coordinated effects and will substantially impede effective competition in the Common Market and the EEA for the endovascular stents. .

(b) Endovascular accessories

324. Both J&J and Guidant sell endovascular guiding catheters, Steerable Guidewires and PTA Balloon Catheters in the EEA.

(1) Steerable Guidewire

325. In 2004, sales of Steerable Guidewires in Europe were worth around € […]*. At EEA level, the parties' combined share was [0-10]*% in 2004 (J&J [0-5%]* and Guidant [0-5%]*). In none of the Member States, there would be a combined market share above [25-35%]*. Moreover, the customers' survey revealed that there are two strong alternative suppliers, being Boston Scientific and Terumo. Therefore, the merger will not result in a significant impediment to effective competition in the common market for Steerable Guidewires

(2) Endovascular Guiding Catheters

326. Sales of endovascular guiding catheters in Europe are relatively small. In 2004, sales were worth around € […]* million. At EEA level, the parties' combined share of guiding catheters was [50-60%]* in 2004 (J&J [40-50%]* and Guidant [0-10%]*). In the EEA, J&J's share is in the range of [40-50%]*. The accretion of market share following the merger will be around [5-15%]*, equivalent to Guidant's position in the

184 Question 57: "*Please explain your possible concerns (if any) in detail*."

EEA. At national level, six markets will be more impacted by the transaction with a combined market share ranging from [40-50%]* to [80-90%]* (Belgium, Germany, Greece, Luxembourg, Netherlands and Spain). Nevertheless, the market investigation, both from the supply and demand sides, confirmed that effective competition will not be significantly impeded due to several factors.

327. First, Guidant has a limited product line, no unique technology and a market share below [5-15%]* EEA wide. Secondly, there are a number of competing suppliers with equivalent or better technology and higher EEA shares. Third, barriers to entry and expansion in the market for guiding catheters are low, and there are no blocking patents or other intellectual property barriers. Customers can easily change suppliers without incurring substantial switching costs, as one supplier's guiding catheter is perfectly interchangeable with competing guiding catheters that have the same specifications and as most hospitals pursue multi-sourcing policies in any event. For these reasons, were the merged entity to seek to increase its prices, the parties' competitors would all expect to win market share and so defeat the attempted price increase.

328. Additionally, the market investigation has confirmed that endovascular guiding catheters present characteristics that make them increasingly commodity-like: a fair degree of homogeneity, very little specific IP content, interchangeability between products of different brands, interoperability with other accessories, low switching costs.

329. Taking these characteristics into account, the Commission concludes that the concentration will not confer increased market power to the merged entity, and that effective competition will be assured in the common market for endovascular guiding catheters.

(3) PTA Balloon Catheters

330. Sales of endovascular PTA balloon catheters in Europe, in 2004, were worth around €[…]* million. J&J' merchant share was [25-35%]* EEA-wide, Guidant's merchant share was [0-10%]* in 2004. The parties' combined share amounted to [35-45%]*. At national level, three markets will be more impacted by the transaction with a combined market share ranging from [35-45%]* to [65-75%]* (Austria, Germany, and Netherlands).

331. Like for endovascular guiding catheters, the market inquiry confirmed that PTA balloon catheters are perceived as commodity-like, with the exception of a new segment, i.e. balloons for small vessels. Moreover, remaining competitors, namely Bard and Boston Scientific with other local suppliers, will constitute a sufficient competitive constraint such as to prevent a unilateral increase in prices by the merged entity. In light of the above, the merger does not give rise to a significant impediment of effective competition in the common markets and the EEA for PTA balloon catheters.

(c) Embolic protection devices

332. J&J and Guidant both offer EPDs in the EEA. Sales of Embolic Protection Devices in Europe, in 2004, were worth around € […]* million. It has to be noticed that in 2001 the sales were substantially lower (around € […]* million).

333. At EEA level, the parties' combined share of Embolic Protection Devices was [20-30%]* in 2004 (J&J [10-20%]* and Guidant [10-20%]*). Whilst, Guidant freshly entered this market successfully reaching a market share of [10-20%]* EEA-wide in two years, it seems that this gain cannibalised J&J's position. The above market shares reflect by and large the situation at national level, with only a couple of exceptions (in Portugal and Poland combined market share range from [50-60%]* to [60-70%]*).

334. The market investigation did not bring evidence that the transaction would impede effective competition in the common market. The combined entity's market share will be relatively modest in the great majority of the countries of the EU, and in any event the competitor Boston Scientific will remain uncontested market leader at the European level in all of the countries of the EU affected.

C. THE RISKS OF FORECLOSURE EFFECTS

335. In its investigation the Commission has also assessed whether, due to the overall impact of the merger across complementary product markets, the transaction could give rise to foreclosure effects as a result of bundling practices by the merging entity.

336. In the field of interventional cardiology Guidant has an attractive portfolio of cardiac medical devices, it is market leader in steerable guidewires and one of the leading suppliers of BMS in Europe, while retaining a non negligible presence in all the other interventional cardiology devices. J&J is present across all the segments, and is strong in DES. The merger gives the new entity a stronger (all relevant segments are covered with a very significant presence, on average above 40-50%) and broader portfolio in the area of interventional cardiology across Europe.

337. Table S below lists those countries in the EEA where the range effect is more pronounced.

Table S

Member State	BMS	DES	BC	GC	SG
Austria	[30-40]*	[40-50]*	[40-50]*	[40-50]*	[80-90]*
Belgium	[50-60]*	[40-50]*	[30-40]*	[20-30]*	[65-75]*
Czech Rep.	[10-20]*	[70-80]*	[35-45]*	[65-75]*	[90-100]*
Denmark	[45-55]*	[60-70]*	[20-30]*	[20-30]*	[50-60]*
France	[30-40]*	[50-60]*	[20-30]*	[35-45]*	[80-90]*
Germany	[50-60]*	[40-50]*	[20-30]*	[40-50]*	[70-80]*
Greece	[20-30]*	[70-80]*	[20-30]*	[50-60]*	[80-90]*
Italy	[35-45]*	[50-60]*	[30-40]*	[40-50]*	[70-80]*
Latvia	[40-50]*	[60-70]*	[0-10]*	[50-60]*	[30-40]*
Malta	[10-20]*	[90-100]*	[80-90]*	[90-100]*	[90-100]*
Poland	[50-60]*	[30-40]*	[30-40]*	[30-40]*	[90-100]*
Portugal	[30-40]*	[50-60]*	[20-30]*	[40-50]*	[70-80]*
Slovakia	[05-15]*	[60-70]*	[60-70]*	[80-90]*	[75-85]*
Spain	[40-50]*	[40-50]*	[30-40]*	[30-40]*	[80-90]*
UK	[40-50]*	[20-30]*	[30-40]*	[35-45]*	[60-70]*

Source: Parties' data validated by the market investigation. – market shares based on value

338. Also in the endovascular devices markets, the merger strengthens the parties' product range. The new entity will have significant markets shares as explained above, in particular for carotid stents, BX stents and guiding catheters. The table at the paragraph

235 above lists those countries in the EEA where the range effect as defined above is more pronounced for the endovascular area.

339. In order to assess the risk of foreclosure effects stemming from the merger, the Commission has considered whether the merging entity has the ability and the incentive to engage in bundling practices, and if so, whether such a strategy could give rise to foreclosure effects.

340. With regard to the ability of the merging entity to engage in bundling practices, the investigation has revealed that package sales occur in the interventional cardiology and endovascular industry, although they are not a dominant feature (according to the Commission estimates, they count on average about 30% of the total sales in Europe). The investigation has also shown that tendering procedures involving single items are widespread and that hospitals generally resort to dual sourcing practices in order to avoid dependence from suppliers.

341. More importantly, as to the possibility for the merging entity to engage in such practices with a view to foreclosing its rivals, the investigation shows that a bundling strategy can be matched by a number of competitors in a successful way. For the interventional cardiology, at least two players, namely Boston and Medtronic have indeed an equally broad portfolio to match the merging entity product range. With regard to the endovascular area, Boston may certainly replicate such strategy and to a lesser extent Medtronic and Bard as well. Moreover, depending of the countries concerned, smaller players can in principle replicate a bundling strategy.

342. The Commission has also enquired whether a bundling strategy could actually involve devices belonging to different areas, such as endovascular, interventional cardiology, and Cardiac management system devices (defibrillators and pacemakers). On this point, the evidence collected in the investigation shows that a broader bundling involving products of different areas is hardly feasible as customers are generally not the same.

343. In light of the above considerations, the transaction does not give rise to risk of foreclosure effects as a result of bundling strategies.

D. CARDIAC SURGERY

1) The parties' activities

344. J&J is active in cardiac surgery mainly through CardioVations (a business unit of J&J's division Ethicon, Inc.). In Europe, J&J supplies the following devices for cardiac surgery: (i) minimally invasive access devices for valve surgery, (ii) stabilisation systems for beating-heart surgery, (iii) stabilisation system accessories, (iv) endoscopic vessel harvesting devices, (v) devices for non-surgical ablation (this latter product is sold by its Biosence Webster, a J&J subsidiary).

345. In 2004, CardioVations had worldwide sales of $[…]* million, of which €[…]* million ($[…]* million) were in the EEA.

346. Guidant produces and sells the following products for cardiac surgery in the EEA: (i) stabilisation systems for beating-heart surgery, (ii) stabilisation system accessories, (iii) anastomosis assistance devices, and (iv) devices for surgical ablation.

347. Guidant's worldwide sales of cardiac surgery devices were $ […]* million in 2004. Sales in the EEA were € […]* million ($ […]*million).

2) Endoscopic vessel harvesting system

348. The EEA sales of EVH systems amounted to € […]* according to the parties and show a growing trend. In Europe, traditional vessel harvesting is used in the large majority (98%) of procedures, which explains the small dimensions of the market. However, this minimally invasive procedure is forecast to increase its penetration over time (as a comparison, the rate of penetration in the USA is around 50%).

349. J&J and Guidant are virtually the only two suppliers of EVH systems, with market shares estimated at 90-95% by the parties and 100% by market players across Europe. The only current competitor in the market was until recently the German supplier Karl Storz. Recently the Japanese company Terumo has launched a EHV system in Europe.

350. The market investigation has confirmed that the proposed merger will result in creation of a virtual monopoly for EVH systems across Europe[185]. In particular, the respondents to the market investigation confirm that the merger will put together the only two choices available on the market[186], and no real, well tested alternative will be left on the market. Furthermore, they emphasise that the J&J's and Guidant EVH systems are based on similar technology, hinting that they should be regarded as close substitutes[187]. Moreover, while there is consensus that the EVH is going to grow significantly within few years, the market is concerned that the evolution of new EVH technologies may slow due to lack of competition[188]. In this respect, the merger removes the most dynamic and innovative player from the market, further raising the entry barriers for new comers[189].

351. In the light of the above, the merger will give rise to a dominant position and significantly impede effective competition in the common market and the EEA for EVH. […]* and they have committed to address it by an adequate remedy.

3) Beating-Heart Stabilisation Systems

352. The EEA sales of beating-heart stabilisation systems amounted to €[…]* million according to the parties, with a negative trend over the past few years. The negative trend is linked to the decrease in CABG procedures imputable to the growing popularity of minimally invasive interventional cardiology procedures. Within this declining trend of CABG, beating-heart procedures are becoming more frequent, although traditional CABG surgery with the use of drugs to stop the heart and a heart-lung machine is still used in the great majority of procedures.

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185 Questionnaire to customers Cardiac Surgery, 6484, 6.4.2005, question 18

186 Questionnaire to customers Cardiac Surgery, 6489, 5..4.2005, question 18

187 See reply to Questionnaire to customers, Cardiac Surgery, folio n. 11567, dated 17 June 2005.

188 See reply to Questionnaire to customers, Cardiac Surgery, folio n. 7109, 15.4.2005, question 20; Questionnaire to customers Cardiac Surgery, 6484, 6.4.2005, question 19.

189 Questionnaire to customers Cardiac Surgery, 6795, 11.4.2005, question 19.

353. Both Guidant and J&J (through the subsidiary CardioVations) are present in the market; Medtronic is their main competitor in Europe. According to the parties, J&J has sales only in Czech Republic, France, Germany, Italy, The Netherlands, Poland and Spain, and achieved in 2004 market share that nowhere exceeded [<5%]*. Its EEA market share is lower than [<5%]*. On the contrary, Guidant presence is much stronger, with an EEA market share of [20-30%]*, number one position in Austria, Germany and Spain, and number two position in the other European markets. Medtronic is market leader in Europe, with an estimated market share of [55-65%]* and number one position in most European countries.

354. The market investigation has broadly confirmed that the merger gives rise to a modest accretion in market shares. Furthermore, despite the recent launch of a new product, J&J has not considerably increased its presence on the market. For these reasons, the Commission concludes that the transaction will not impede effective competition in the common market.

4) Blowers/Misters

355. The parties submit that the EEA market of these products is very small in value (around € […]* million in 2004). Guidant's sales amounted in 2004 to less than € […]* and J&J to around € […]*, which make a combined market share of around [25-35%]* in value. According to the parties, overlaps exist in only three Member States: Czech Republic, with a combined market share of [75-85%]* ([25-35%]* J&J and [45-55%]* Guidant), Germany with a combined market share of [35-45%]* ([5-15%]* J&J and [25-35%]* Guidant) and UK with a combined market share of [30-40%]* ([10-20%]* J&J and [10-20%]* Guidant).

356. The market investigation has indicated that blowers and misters are low value commodity accessories, that various alternatives to the products of the parties exist in all national markets, and that in some countries (e.g. the Czech Republic), physicians are accustomed to use custom made devices by the hospital itself. Based on these elements, the Commission concludes that the transaction will not impede effective competition in the common market.

VII. COMMITMENTS SUBMITTED BY THE PARTIES

1) Description of the commitments

357. In order to render the concentration compatible with the common market, the parties have entered into some commitments pursuant to Article 8(2) of the EC Merger Regulation, which are annexed to this Decision. The commitment package was proposed by the parties on 13 July 2005.

358. The parties' commitments consist of :

(a) In the Steerable Guidewires business, the parties propose to divest the assets associated predominantly with the supply, marketing and sale of J&J's 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 license 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, sterilization (these operations are

currently outsourced by J&J to a third party), distribution and warehousing (see schedule on guidewires for a more detailed description).

(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 in the EEA. The divestment does not include manufacturing, finance, administration, R&D, regulatory, quality and clinical research teams, which are based in the US and operate on a worldwide basis (see schedule on endovascular devices for a more detailed description). 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 US 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 any of the following:

(i) J&J's Endoscopic Vessel Harvesting products ("EVH") and endoscopic radial artery harvesting ("ERA kits"); or

(ii) Guidant worldwide assets and personnel of Cardiac Surgery business division; or

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

2) Suitability for removing the competition concerns

359. As to the commitment proposed in the area of IC guidewires, the divestiture of J&J's business in Europe to a suitable purchaser is structural in nature and is designed to entirely remove the overlaps resulting from the merger. The business to be divested does not include any manufacturing, as J&J sources its guidewires from an OEM manufacturer. However, the fact that no manufacturing facilities are being divested does not appear to be a concern for the viability of the divestment business. Many guidewires suppliers, including J&J, source from OEM manufacturers. The market investigation has confirmed that the divestment business can operate in a viable way without manufacturing, and that the commitment proposed by the parties addresses the competition concerns identified by the Commission.

360. As to the commitment proposed in the area of cardiac surgery, the divestiture of either one of the parties' EVH worldwide business, or, as a fall-back solution, the divestiture of Guidant worldwide cardiac surgery business to a suitable purchaser are structural in nature and are designed to entirely remove the overlaps resulting from the merger. As to the viability of the divestments business, some of the respondents to the market testing have noted that the perimeter of the assets relating to the divestment business of the parties' first option (divestiture of one of the parties' EVH business) may be too limited and have little value, thus undermining the prospect of success of the divestiture. In this respect, it should be noted that the existence of a fall-back, "crown jewels" solution, consisting of divesting the whole of Guidant's cardiac surgery business constitutes a sound safeguard towards any risk of failure of the first remedy. Moreover, the

commitments proposed by the parties are also meant to address the competition concerns identified by US FTC in the US territory. In this regard, the first and more limited divestiture proposed by the parties is agreeable to the FTC only to the extent it takes the form of an upfront divestiture, i.e. prior to the closing of the merger. This removes any risk that the above commitment may later prove to be unsuccessful.

361. As to the commitment proposed in the endovascular area, the divestiture of Guidant's endovascular business in Europe to a suitable purchaser is structural in nature and is designed to entirely remove the overlaps resulting from the merger. As said above, the divestment business does not include the upstream activities of manufacturing and R&D, which are based in the US and operate on a worldwide basis. On this aspect, most respondents to the market testing consider that the lack of manufacturing facilities and clinical research teams in the divestment business is not necessarily a concern to the extent the purchaser is an incumbent player in this area and can rely upon its own complementary assets. Other respondents, mostly the smaller players, have instead expressed some concerns that the divestiture of a downstream business disconnected from manufacturing and R&D may undermine the viability of the business. The Commission is of the view that the undertakings proposed by the parties, having also regard to the additional refinements that have been crafted as a result of the market testing, adequately address the above issues. In this regard, the parties commit to a specific obligation to assist the purchaser in building up its own manufacturing capabilities in a foreseeable, precise and relatively short time frame ([…]*). In the interim period, the parties also commit to supply the finished products under commercial terms favourable to the purchaser (costs plus margins consistent with the industry standard, plus a discount). Moreover, during the transitional period, the parties commit to prioritise the purchaser's supplies and to timely delivery. The interim obligations borne by the parties should enable the purchaser to run the divestment business in a viable manner from the outset and without disruption. Moreover, these obligations are such to create upon the parties a strong incentive to properly and quickly implement the undertaking and put to an end the transitional supply agreement. As to R&D, the parties commit to a specific obligation to transfer in a proper and intelligible manner the clinical research and the data relating to the pipeline products being divested to the purchaser. Moreover, the parties have an additional obligation to share with the purchaser any other data or research they may develop with respect to the pipeline products being divested to the purchaser. In the light of the above, the commitment proposed by the parties addresses the significant restrictions on competition resulting from the concentration.

3) Conclusion on the commitments

362. The Commission therefore considers the commitments suitable for remedying the significant impediments to effective competition in the Common Market and the EEA resulting from the operation, which have been established in the previous sections of this Decision.

VIII. CONDITIONS AND OBLIGATIONS

363. Under the first sentence of the second subparagraph of Article 8(2) of the Merger Regulation, the Commission may attach to its decision conditions and obligations intended to ensure that the undertakings concerned comply with the commitments they

have entered into vis-à-vis the Commission with a view to rendering the concentration compatible with the common market.

364. The achievement of the measure that gives rise to the structural change of the market is a condition, whereas the implementing steps which are necessary to achieve this result are generally obligations on the parties. Where a condition is not fulfilled, the Commission's decision declaring the concentration compatible with the common market no longer stands. Where the undertakings concerned commit a breach of an obligation, the Commission may revoke the clearance decision in accordance with Article 8(5) of the Merger Regulation. The undertakings concerned may also be subject to fines and periodic penalty payments under Articles 14(2) and 15(1) of the Merger Regulation.

365. In accordance with the basic distinction described above, the decision in this case is conditioned on the full compliance with the conditions set out in Section B of the Commitments submitted by the parties on 13 July 2005 (i.e. divestiture of J&J's Steerable Guidewires EEA business; divestiture of Guidant's entire EEA endovascular business; divestiture of alternatively either J&J's EVH and ERA kits or Guidant worldwide assets and personnel of Cardiac Surgery business division or Guidant's EVH kits.)

366. The remaining requirements set out in the other Sections of the Commitments submitted by the parties on 13 July 2005 are considered to constitute obligations.

IX. OVERALL CONCLUSION

367. 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 pursuant to Article 2(2) of Council Regulation (EC) No 139/2004, subject to full compliance with the commitments as described in paragraph 358 and the related text in the Commitments annexed to this Decision.

HAS ADOPTED THIS DECISION:

Article 1

The notified operation whereby Johnson&Johnson would acquire sole control of Guidant is hereby declared compatible with the common market and with the functioning of the EEA Agreement.

Article 2

Article 1 is subject to full compliance with the conditions set out in Section B of the Commitments submitted by the parties on 13 July 2005, contained in the Annex.

Article 3

Article 1 is subject to full compliance with the obligations set out in Section A, and in Sections C to G , of the Commitments submitted by the parties on 13 July 2005.

Article 4

This Decision is addressed to:

Johnson&Johnson
One Johnson & Johnson Plaza
New Brunswick
New Jersey 08933
U.S.A.

Done at Brussels, 25/08/2005

For the Commission

Neelie KROES
Member of the Commission

CASE No. COMP/M.3687 – Johnson & Johnson/Guidant

Commitments to the European Commission

Pursuant to Article 8(2) of Council Regulation (EC) No. 139/2004 (the "**Merger Regulation**"), Johnson & Johnson ("**J&J**") hereby provides the following commitments (the "**Commitments**") in order to enable the European Commission (the "**Commission**") to declare the acquisition of Guidant Corporation ("**Guidant**"; J&J and Guidant jointly referred to as the **"Parties"**) compatible with the common market and the EEA Agreement.

The Commitments shall take effect upon the date of adoption of the Commission Decision pursuant to Article 8(2) of the Merger Regulation in this case (the "**Decision**") but will be subject to the closing of J&J's acquisition of Guidant.

This text shall be interpreted in the light of the Decision, within the general framework of Community law, in particular the Merger Regulation and by reference to the Commission Notice on remedies acceptable under the Merger Regulation.

Section A. Definitions

For the purpose of the Commitments, the following terms shall have the following meaning:

Affiliated Undertakings: undertakings controlled by J&J, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in the light of the Commission Notice on the concept of concentration under the Merger Regulation.

Closing: with regard to each Divestment Business, the transfer to the Purchaser of legal title of the assets, and/or the execution of the license, transfer or assignments of rights currently held by the Parties, and/or the transfer of agreements, as necessary or appropriate.

Cordis: Cordis Corporation, an Affiliated Undertaking, incorporated under the laws of Florida, with its registered office at 14201 NW 60TH Avenue, P.O. Box 025700, Miami Lakes, Florida 33014, USA.

Divestment Businesses: the assets comprising the businesses that J&J commits to divest, as defined in Section B and the attached Schedules (each respective business defined in Schedules I, II and III herein referred to as a **"Divestment Business"**).

Divestiture Trustee: one or more natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by J&J and who has received from J&J the exclusive mandate to sell one or more of the Divestment Businesses to a Purchaser at no minimum price.

Effective Date: the date of the Decision.

Ethicon: Ethicon, Inc., an Affiliated Undertaking, incorporated under the laws of New Jersey, with its registered office at Route 22 West, Somerville, New Jersey 08876, USA.

Extended Divestiture Period: [BUSINESS SECRET] from the date of expiry of the First Divestiture Period within which the Divestiture Trustee shall have the irrevocable and exclusive mandate from J&J to sell those Divestment Businesses for which a binding agreement is not yet concluded at the end of the First Divestiture Period.

First Divestiture Period: [BUSINESS SECRET] within which J&J may conclude one or more binding agreements to sell the Divestment Businesses before providing a mandate to the Divestiture Trustee.

Hold Separate Manager: the person appointed by J&J to manage the day-to-day business of any Divestment Business that is held separate pursuant to paragraph 7, under the supervision of the Monitoring Trustee.

J&J: Johnson & Johnson, incorporated under the laws of New Jersey, with its registered office at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, USA.

Key Personnel: all personnel necessary to maintain the viability and competitiveness of the Divestment Businesses, as listed in the applicable Schedule.

Monitoring Trustee: one or more natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by J&J, and who has the duty to monitor J&J's compliance with the conditions and obligations attached to the Decision.

Personnel: the personnel listed in the applicable Schedule.

Purchaser: with regard to each Divestment Business, the undertaking approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee.

Section B. The Divestiture commitment

Commitment to divest

1. In order to restore effective competition, J&J commits to divest, or procure the divestiture of, the Divestment Businesses on terms of sale approved by the Commission in accordance with the procedure described in paragraph 16 (the "**Divestiture Commitment**"). J&J commits to do so by the end of the Extended Divestiture Period. To carry out the divestiture, J&J shall seek to find, for each Divestment Business, a Purchaser and to enter into a final binding agreement for the sale of such Divestment Business within the First Divestiture Period. If J&J has not entered into such an agreement at the end of the First Divestiture Period, J&J shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business within the Extended Divestiture Period in accordance with the procedure described in paragraph 26.

2. J&J shall be deemed to have complied with the Divestiture Commitment if, (i) by the end of the Extended Divestiture Period, J&J or an Affiliated Undertaking has entered into a final binding sale and purchase agreement for each Divestment Business; (ii) the Commission approves the Purchasers and the terms in accordance with the procedure described in paragraphs 15 and 16; and (iii) Closings take place in each case within a period not exceeding [BUSINESS SECRET] after the approval of the Purchaser and the terms of sale by the Commission.

3. In order to maintain the structural effect of the Divestiture Commitment, J&J shall, for a period of ten (10) years after the Effective Date, not acquire direct or indirect influence over the whole or part of any of the Divestment Businesses, unless the Commission has previously found that the market structure has changed to such an extent that the absence

of influence over the Divestment Business in question is no longer necessary to render the proposed concentration compatible with the Merger Regulation.

4. [BUSINESS SECRET]

The Divestment Business(es)

5. The divestiture of the Divestment Businesses will proceed by way of asset transactions (including transfer, sale, assignment, license, as the case may be). As a general rule, each divestiture transaction shall include the following elements, as more specifically defined in the relevant Schedule:

(i) those tangible and intangible assets (including intellectual property rights), by way of transfer, sale, assignment or license, which are necessary to ensure the viability and competitiveness of the Divestment Business;

(ii) licences, permits and authorisations issued by any governmental organisation for the exclusive benefit of the Divestment Business;

(iii) contracts, leases, commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business to the extent legally transferable;

(iv) the Personnel, but only if specified in the applicable Schedule;

(v) at the option of the Purchaser, transitional agreements with Affiliated Undertakings for the supply or distribution of products and/or technical assistance.

Section C. Related commitments

Preservation of viability, marketability and competitiveness

6. From the Effective Date until Closing, J&J shall preserve the economic viability, marketability and competitiveness of each Divestment Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential. In particular J&J commits:

(a) not to carry out any act upon its own authority that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;

(b) to make available sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans;

(c) to take all reasonable steps, including appropriate incentive schemes (based on industry practice), to encourage Key Personnel to remain with the Divestment Business, if applicable.

Hold separate obligations

7. If the Divestment Business is a former Guidant business, J&J commits, from the Effective Date until Closing and subject to paragraph 6, to (a) keep the Divestment Business

separate from the businesses it is retaining; (b) ensure that Key Personnel (if applicable) of the Divestment Business - including the Hold Separate Manager - have no involvement in any retained business and vice versa; and (c) ensure that the Personnel do not report to any individual outside the Divestment Business (if applicable).

8. If the Divestment Business is a former Guidant business, prior to Closing, J&J shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed as a distinct and saleable entity separate from the businesses it is retaining. If the Divestment Business is a former Guidant Business, J&J shall also appoint a Hold Separate Manager who shall be responsible for the management of the Divestment Business, under the supervision of the Monitoring Trustee. The Hold Separate Manager shall manage the Divestment Business in the best interest of the business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by J&J.

9. If the Divestment Business is not a former Guidant business, to ensure that the Divestment Business is managed as a going concern in its best interests with a view to its sale, the Monitoring Trustee shall have the additional duties and obligations described in paragraph 25 (b)(iv).

Ring-fencing

10. If the Divestment Business is a former Guidant business, J&J shall implement all necessary measures to ensure that it does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to that Divestment Business. However, J&J may obtain information relating to such Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or whose disclosure to J&J is required by law.

Non-solicitation clause

11. J&J undertakes, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Key Personnel transferred with any Divestment Business for a period of [BUSINESS SECRET] after Closing.

Due diligence

12. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Businesses, J&J shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process, (i) provide to potential purchasers sufficient information as regards the relevant Divestment Business; and (ii) provide to potential purchasers sufficient information relating to the Personnel and allow them reasonable access to the Personnel.

Reporting

13. J&J shall submit written reports in English on potential purchasers of the Divestment Businesses and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than ten (10) days after the end of every month following the Effective Date (or otherwise at the Commission's request).

14. To the extent this will occur after the Effective Date, J&J shall inform the Commission and the Monitoring Trustee on the preparation of data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. The Purchaser

15. In order to ensure the immediate restoration of effective competition, the Purchaser, in order to be approved by the Commission, must:

(a) be independent of and unconnected to the Parties;

(b) have the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors;

(c) neither be likely to create, in the light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Divestiture Commitment will be delayed, and must, in particular, reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business (the before-mentioned criteria for the purchaser hereafter the "**Purchaser Requirements**").

16. The final binding sale and purchase agreement shall be conditional on the Commission's approval. When J&J has reached an agreement with a Purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), to the Commission and the Monitoring Trustee. J&J must be able to demonstrate to the Commission that the Purchaser meets the Purchaser Requirements and that the Divestment Business is being sold in a manner consistent with the Divestiture Commitment. For the approval, the Commission shall verify that the Purchaser fulfils the Purchaser Requirements and that the Divestment Business is being sold in a manner consistent with the Divestiture Commitment. In the event that J&J receives offers from more than one potential purchaser which, upon verification by the Commission, fulfil the Purchaser Requirements, J&J shall be free to take whichever offer that J&J deems the most appropriate to its interests. The Commission may approve the sale of the Divestment Business without one or more assets or members of the Personnel, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed Purchaser.

Section E. Trustee

I. Appointment procedure

17. J&J shall appoint a Monitoring Trustee to carry out the functions specified below with regard to the Monitoring Trustee.

18. If J&J has not entered into a binding sale and purchase agreement one (1) month before the end of the First Divestiture Period or if the Commission has rejected a Purchaser proposed by J&J at that time or thereafter, J&J shall appoint a Divestiture Trustee to carry

out the functions specified below with regard to the Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Extended Divestiture Period.

19. The Trustee(s) shall be independent of the Parties, possess the necessary qualifications to carry out its mandate, for example as an investment bank or consultant or auditor, and shall neither have nor become exposed to a conflict of interest. The Trustee(s) shall be remunerated by J&J in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, the fee shall also be linked to a divestiture within the Extended Divestiture Period.

Proposal by J&J

20. No later than one (1) week after the Effective Date, J&J shall submit to the Commission for approval a list of one or more persons whom J&J proposes to appoint as the Monitoring Trustee. No later than one (1) month before the end of the First Divestiture Period, J&J shall submit to the Commission for approval a list of one or more persons whom J&J proposes to appoint as Divestiture Trustee. The proposal shall contain sufficient information for the Commission to verify that the proposed entities fulfil the requirements set out in paragraph 19 and shall include:

(a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

(b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks;

(c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different Trustees are proposed for the two functions.

Approval or rejection by the Commission

21. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, J&J shall appoint or cause to be appointed, the individual or institution concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, J&J shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by J&J

22. If all the proposed Trustees are rejected, J&J shall submit the names of at least two (2) more individuals or institutions within one (1) week of being informed of the rejection, in accordance with the requirements and the procedure set out in paragraph 20.

Trustee nominated by the Commission

23. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom J&J shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

24. The Trustee shall assume its specified duties in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or J&J, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

25. The Monitoring Trustee shall:

(a) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.

(b) oversee the ongoing management of each of the Divestment Businesses with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by J&J with the conditions and obligations attached to the Decision, and in particular shall:

(i) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Businesses in accordance with paragraph 6;

(ii) if the Divestment Business is a former Guidant business, ensure that the Divestment Business is kept separate from the businesses retained by J&J, in accordance with paragraph 7;

(iii) if the Divestment Business is a former Guidant business, supervise the management of the Divestment Business as a saleable entity, in accordance with paragraph 8;

(iv) if the Divestment Business is not a former Guidant business, ensure that the Divestment Business is managed as a going concern in the best interests of the Divestment Business with a view to its sale;

(v) if the Divestment Business is a former Guidant business, (a) in consultation with J&J, determine all necessary measures to ensure that J&J does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to that Divestment Business and (b) decide whether such information may be disclosed to J&J as its disclosure is reasonably necessary to allow J&J to carry out the divestiture or as the disclosure is required by law;

(vi) monitor the splitting of assets and the allocation of Personnel between the Divestment Business and J&J or Affiliated Undertakings.

(c) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision, including the monitoring of the implementation of the technical assistance agreement and the supply agreement referred to in Schedule III.

(d) propose to J&J such measures as the Monitoring Trustee considers necessary to ensure J&J's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Businesses, the holding separate of Divestment Businesses that were former Guidant businesses and the non-disclosure of competitively sensitive information.

(e) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process, (i) potential purchasers receive sufficient information relating to the Divestment Business and the Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process; and (ii) potential purchasers are granted reasonable access to the Personnel.

(f) provide to the Commission, sending J&J a non-confidential copy at the same time, a written report within fifteen (15) days after the end of every month. The report shall cover the operation and management of the Divestment Business so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers. In addition to these reports, the Monitoring Trustee shall promptly report in writing to the Commission, sending J&J a non-confidential copy at the same time, if it concludes on reasonable grounds that J&J is failing to comply with these Commitments.

(g) within one week after receipt of the documented proposal referred to in paragraph 16, submit to the Commission a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of the Divestment Business without one or more assets or not all of the Personnel affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser.

Duties and obligations of the Divestiture Trustee

26. Within the Extended Divestiture Period, the Divestiture Trustee shall sell at no minimum price any Divestment Business that remains unsold to a Purchaser, provided that the Commission has approved both the Purchaser and the final binding sale and purchase agreement in accordance with the procedure laid down in paragraph 16. The Divestiture Trustee shall include in the sale and purchase agreement such terms and conditions as it considers appropriate for an expedient sale in the Extended Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of J&J, subject to J&J's unconditional obligation to divest at no minimum price in the Extended Divestiture Period.

27. In the Extended Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within fifteen (15) days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to J&J.

III. Duties and obligations of J&J

28. J&J shall provide and shall cause its advisors to provide the Trustee with all such co-operation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of J&J's or the Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and J&J and the Divestment Business shall provide the Trustee upon request with copies of any document. The Trustee shall agree in writing to keep any confidential information and business secrets disclosed to it in confidence, except to the extent necessary to perform its duties hereunder. J&J and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

29. J&J shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. J&J shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. J&J shall inform the Monitoring Trustee on possible purchasers, submit a list of potential purchasers, and keep the Monitoring Trustee informed of all developments in the divestiture process.

30. J&J shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale, the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, J&J shall cause the documents required for effecting the sale and the Closing to be duly executed.

31. J&J shall indemnify the Trustee and its employees and agents (each an "**Indemnified Party**") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to J&J for, any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

32. At the expense of J&J, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to J&J approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should J&J refuse to approve the advisors proposed by the Trustee the Commission may approve the

appointment of such advisors instead, after having heard J&J. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 31 shall apply mutatis mutandis. In the Extended Divestiture Period, the Divestiture Trustee may use advisors who served J&J during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

IV. Replacement, discharge and reappointment of the Trustee

33. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a conflict of interest:

(i) The Commission may, after hearing the Trustee, require J&J to replace the Trustee; or

(ii) J&J, with the prior approval of the Commission, may replace the Trustee.

34. If the Trustee is removed according to paragraph 33, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full handover of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 17 through 23.

35. Beside the removal according to paragraph 33, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. Dispute resolution

36. Should a dispute arise between J&J and the Purchaser regarding the implementation of any term of the technical assistance agreement or the supply arrangement referred to in Schedule III, such dispute shall be submitted to a fast track resolution procedure (the **"Fast Track Resolution Procedure"**).

37. The Fast Track Resolution Procedure will operate as follows:

(i) The party who seeks to initiate the Procedure (the "Initiating Party") shall notify the other party (the "Other Party") of its request and specify the reasons why it believes that a failure by the Other Party to meet such request would be inconsistent with these Commitments.

(ii) The Purchaser and J&J (including the relevant Affiliated Undertaking) shall use their best efforts to resolve all differences of opinion and to settle all disputes that may arise through co-operation and consultation within a reasonable period of time not to exceed fifteen (15) calendar days.

(iii) Should the Purchaser and J&J fail to resolve their differences of opinion through co-operation and consultation, the Initiating Party shall within seven (7) days initiate an arbitration process.

(iv) To initiate the arbitration process, the Initiating Party shall give written notice to the Other Party nominating an arbitrator and stating the specific nature of the claim, the factual basis of its position and the relief requested. In such case, the Other Party shall appoint another arbitrator within fourteen (14) calendar days after receipt of

the written notice. The arbitrators so appointed shall appoint a third arbitrator to be president of the arbitration tribunal within seven (7) calendar days after both arbitrators have been nominated. If the arbitrators nominated by the Purchaser and J&J cannot agree on the nomination of a third arbitrator, they shall request that the London Court of International Arbitration appoint the third arbitrator.

(v) Any of the arbitrators will be entitled to request any relevant information from the Purchaser or J&J. The arbitrators shall agree in writing to keep any confidential information and business secrets disclosed to them in confidence. Throughout these Commitments the standards attributed to confidential information and business secrets are those as set out in accordance with European Community law.

(vi) The burden of proof in any dispute governed by this Section shall be as follows: (i) the Initiating Party must produce evidence of a prima facie case, and (ii) if the Initiating Party produces evidence of a prima facie case, the arbitrators must find in favour of the Initiating Party unless the Other Party can produce evidence to the contrary.

(vii) The arbitration procedure shall follow the Rules of the London Court of International Arbitration. The arbitration shall be conducted in London. The language of the arbitration shall be English. In the event of disagreement between the parties to the arbitration regarding the interpretation of the Commitments, the arbitrators shall inform the Commission and may seek the Commission's interpretation of the Commitments before finding in favour of any party to the arbitration. The Commission may, at any time, issue a submission during the arbitration procedure

(viii) The arbitration award shall, in addition to dealing with the merits of the claim, impose the fees and costs of the prevailing party upon the party that is unsuccessful.

(ix) Decisions of the arbitrators shall be final and binding on all persons submitting to arbitration.

(x) Nothing in the above-described arbitration procedure shall affect the powers of the Commission to take decisions in relation to the Commitments in accordance with its powers under the Merger Regulation and the EC Treaty.

38. The parties shall report to the Commission any matters which the Commission reasonably requests in order to determine whether the parties have complied with the present commitments. Any such report shall be sent to the Commission within fifteen (15) working days from the date the Commission makes a request.

Section G. The review clause

39. The Commission may, where appropriate, in response to a request from J&J showing good cause and accompanied by a report from the Monitoring Trustee:

(i) Grant an extension of a Divestiture Period;

(ii) Allow the transfer of a Divestment Business, without one or more assets or members of the Personnel, where applicable; or

(iii) Waive, modify or substitute, in exceptional circumstances, one or more of the conditions or obligations in these Commitments.

40. Where J&J seeks an extension of a time period, it shall submit a request to the Commission no later than one (1) month before the expiry of that period, showing good cause. Only in exceptional circumstances shall J&J be entitled to request an extension within the last month of any period.

41. If the approval of the J&J/Guidant merger by another antitrust authority is made subject to requirements that (i) are potentially inconsistent with these Commitments or (ii) would, when combined with the obligations in these Commitments, result in the divestiture of assets or businesses beyond that which is necessary to restore effective competition, J&J may request a review and adjustment of these Commitments in order to avoid such inconsistencies or obligations beyond those necessary to restore effective competition.

*****

Name: [BUSINESS SECRET]

Title: [BUSINESS SECRET]

Duly authorised [BUSINESS SECRET]

for and on behalf of Johnson & Johnson

Date: 8 August 2005

Schedule I

Endoscopic Vessel Harvesting

1. J&J commits to procure the divestment to the Purchaser of the Alternative A Divestment Business, the Alternative B Divestment Business, or the Alternative C Divestment Business, each of which is defined below.

Alternative A Divestment Business

2. The Alternative A Divestment Business as operated to date does not constitute a separate legal entity. It consists of the worldwide assets directly and predominantly associated with the development, supply, manufacture, assembly, marketing, distribution and sale of Ethicon's CardioVations endoscopic vessel harvesting products, namely procedural kits for endoscopic vein harvesting ("EVH") and endoscopic radial artery harvesting ("ERA") (together, the "EVH and ERA kits").

3. Following paragraph 5 of the Commitments, this Divestment Business includes:

(a) the following main tangible assets, to the extent that they are owned by Ethicon or other Affiliated Undertakings and relate predominantly to the EVH and ERA kits:

(i) moulds and other tooling used exclusively in connection with the EVH and ERA kits and copies of specifications, drawings and validation documentation for moulds and other tooling related to the EVH and ERA kits;

(ii) existing inventory of finished products held as at Closing;

(iii) copies of any and all design history files, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, quality control standards and regulatory records, save that any parts thereof that do not relate predominantly to the EVH and ERA kits may be redacted from such copies;

(iv) any and all leg and arm models that are used in connection with the EVH and ERA kits for training purposes and copies of any and all training materials that are used for training that is specific to the EVH and ERA kits, save that any parts thereof that do not relate predominantly to the EVH and ERA kits may be redacted from such copies;

(v) copies of any and all current advertising and promotional materials used in connection with the EVH and ERA kits, save that any parts thereof that do not relate predominantly to the EVH and ERA kits may be redacted from such copies;

(vi) copies of any and all scientific and medical articles, market research reports, studies and data, marketing plans, and other marketing-related information and materials that are used in connection with the EVH and ERA kits, save that any parts thereof that do not relate predominantly to the EVH and ERA kits may be redacted from such copies.

(b) the following main intangible assets, to the extent they are owned or licensed by J&J or Affiliated Undertakings:

(i) the assignment of the CLEARGLIDE®, CLEARGLIDE ACCEL™ and Watchband Incision™ trademarks;

(ii) the transfer (by means of withdrawal and re-registration) of all Internet domain names related exclusively to the EVH and ERA kits;

(iii) the assignment of or license to any copyrights to those materials listed in subparagraphs 3(a)(iii) through 3(a)(vi) and paragraph 3(e), save that any parts thereof that do not relate predominantly to the EVH and ERA kits may be excluded from such assignment or license;

(iv) the assignment of the non-exclusive worldwide patent license agreement between Ethicon and CardioThoracic Systems, Inc. (a subsidiary of Guidant), for the manufacture, use and sale of an endoscopic vessel harvesting system;

(v) the exclusive licence, for the field of endoscopic vessel harvesting, of patents and any other intellectual property rights (other than trademarks) protecting the Endopath® Vessel Scissors, the Allport® Clip Applier, the Endoloop® One Tie Vessel Ligator and the atraumatic blunt dissector;

(vi) the assignment of all other intellectual property rights predominantly used in connection with the EVH and ERA kits, subject to J&J receiving a license back insofar as these intellectual property rights are necessary for its retained businesses.

(c) to the extent legally transferable, all governmental licenses, permits, authorisations and registrations relating exclusively to the EVH and ERA kits.

(d) customer lists and credit and other customer records in existence at the date of Closing for the EVH and ERA kits.

(e) copies of all books, ledgers and other business records to the extent related predominantly to the EVH and ERA kits, save that any parts thereof that do not relate to the EVH and ERA kits may be redacted from such copies.

(f) contracts (or portions thereof), to the extent they relate to the EVH and ERA kits, and to the extent they are assignable, it being noted, however, that Ethicon is willing to help the Purchaser obtain assignments of or substitutes for these contracts as they relate to the kits.

(g) the arrangements for the supply of the following products and services by J&J or Affiliated Undertakings:

(i) if required by the Purchaser, the supply on a reasonable cost plus basis to be agreed with the Purchaser, for the specific field of use in procedural kits for endoscopic vessel harvesting, of the Harmonic Scalpel® for a transitional period of up to [BUSINESS SECRET] after Closing;

(ii) if required by the Purchaser, the supply on a reasonable cost plus basis to be agreed with the Purchaser, for the specific field of use in procedural kits for endoscopic vessel harvesting, of the Endoloop® devices (with related sutures) for a transitional period of up to [BUSINESS SECRET] after Closing;

(iii) if required by the Purchaser, the supply on a reasonable cost plus basis to be agreed with the Purchaser, of essential services currently provided by J&J or Affiliated Undertakings for the procurement, manufacture, assembly,

packaging, sterilisation and distribution of the EVH and ERA kits, such services to be provided for a transitional period of up to [BUSINESS SECRET] after Closing.

4. The Divestment Business shall not include:

(a) any facilities of J&J or Affiliated Undertakings, including those used for manufacture, assembly, sterilization, distribution and warehousing of the EVH and ERA kits.

(b) any furniture, fixtures, machinery or other equipment, save as provided for in paragraphs 3(a)(i) and (iv) of this Schedule I.

(c) any trademarks or distinctive signs other than the trademarks listed under paragraph 3(b)(i) of this Schedule I; or any domain names other than the domain names described in paragraph 3(b)(ii) of this Schedule I.

(d) any patents or other intellectual property rights, save as provided for in paragraphs 3(a), 3(b) or 3(e) of this Schedule I.

(e) any bank accounts, cash, accounts receivable, hedging or other currency exchange agreements.

(f) any information management systems, software or hardware.

(g) any personnel, or any personnel-related documents, records, benefit plans or information.

(h) any general books of account and books of original entry that comprise J&J's or an Affiliated Undertaking's permanent accounting or tax records (to the extent necessary for the Divestment Business, redacted copies of such documents will be provided to the Purchaser upon request).

(i) those portions of or rights under contracts that do not relate to the EVH and ERA kits.

(j) any insurance policies, and any claims thereunder arising out of events prior to the Closing.

(k) any rights or assets relating to the Harmonic Scalpel®, beyond an arrangement for the supply of such products for a transitional period not exceeding [BUSINESS SECRET] after Closing.

(l) any rights or assets relating to any sutures, beyond an arrangement for the supply of Endoloop® devices for a transitional period not exceeding [BUSINESS SECRET] after Closing.

(m) any books, records, materials, information or other properties or assets that do not relate predominantly to the EVH and ERA kits.

(n) any authorisations, which may not be transferred by their terms or without the consent of a third person and for which such consent has not been obtained. However, Ethicon shall use its reasonable efforts to obtain such consent.

(o) any assets or properties that are used by Ethicon or Affiliated Undertakings to provide CardioVations and/or Ethicon's other businesses generally with services and support of an overhead, sales, administrative or managerial nature for which costs are allocated among the Divestment Business and other businesses of Ethicon.

Alternative B Divestment Business

5. The Alternative B Divestment Business is composed of three separate legal entities, which embrace the worldwide assets and personnel of Guidant's Cardiac Surgery business division.

6. The cardiac surgery devices constituting this business consist of beating-heart stabilisation products and accessories, endoscopic vessel harvesting devices, anastomotic assistance devices and surgical ablation devices as further detailed in Annex I-A of this Schedule I (the "Cardiac Surgery Products").

7. Following paragraph 5 of the Commitments, this Divestment Business includes:

(a) the following main tangible assets:

(i) manufacturing lines, equipment and other tooling;

(ii) existing inventory of finished products held as at Closing;

(iii) copies of any and all design history files, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, quality control standards and regulatory records;

(iv) any and all models used for training purposes and copies of any and all training materials;

(v) any and all current advertising and promotional materials;

(vi) copies of any and all scientific and medical articles, data results and records of clinical trials, market research reports, studies and data, marketing plans, and other marketing-related information and materials.

(b) the following main intangible assets:

(i) the assignment of the trademarks used exclusively in connection with the Cardiac Surgery Products, including the following trademarks: AXIUS™; FlexLink™; Tri-Slot Socket™; Activator™; Xpose™; ACROBAT™; ULTIMA™; QuickLock™; Epigrip™; VASOVIEW®™; HEARTSTRING™; ACCESS MV™; ACCESS MP™; FLEX 4™; FLEX 10™;

(ii) the grant of a license (including the right to sub-license) for use in the field of cardiac surgery, of any other intellectual property rights (other than trademarks) that, immediately prior to Closing, (i) are owned by Guidant or affiliated undertakings of Guidant, or under which Guidant or its affiliated undertakings have the right to transfer or grant sublicenses to third parties, and (ii) are used by Guidant at that date in connection with the Cardiac Surgery Products. Such license shall be exclusive as against third parties, but shall be subject to any licenses Guidant has granted prior to the date of closing of the J&J/Guidant merger; the license shall be non-exclusive as against J&J (i.e., J&J will be able to exploit the intellectual property itself) if J&J had the right to exploit the intellectual property prior to the J&J/Guidant merger; otherwise the license will be exclusive as against J&J for a period of [BUSINESS SECRET] after the Closing; for the avoidance of doubt, J&J shall, in any event, have the right to exploit the intellectual property outside the field of the Cardiac Surgery Products.

(c) to the extent legally transferable (by way of transfer, assignment or license), all governmental licenses, permits, authorisations and registrations relating to the Cardiac Surgery Products.

(d) customer lists and credit and other customer records in existence at the date of Closing.

(e) copies of all books, ledgers and other business records related to the Cardiac Surgery Products, save that any parts thereof that do not relate to the Cardiac Surgery Products may be redacted from such copies.

(f) the Key Personnel and the Personnel associated with the Cardiac Surgery Products.

8. For the avoidance of doubt, the Divestment Business does not include manufacturing or warehousing facilities.

9. In order to assist a Purchaser to assume responsibility for manufacturing the Cardiac Surgery Products, at the request of the Purchaser, Guidant will provide technical assistance to the Purchaser regarding the installation, qualification and validation of the transferred manufacturing lines and equipment, on a reasonable cost plus basis to be agreed with the Purchaser and supply the Purchaser with its requirements of the Cardiac Surgery Products during such installation, qualification and validation period on a reasonable cost plus basis to be agreed with the Purchaser.

Alternative C Divestment Business

10. The Alternative C Divestment Business as operated to date does not constitute a separate legal entity. It consists of the worldwide assets directly and predominantly associated with the development, supply, manufacture, assembly, marketing, distribution and sale of Guidant's endoscopic vessel harvesting products, namely procedural kits for endoscopic vessel harvesting ("EVH kits").

11. Following paragraph 5 of the Commitments, this Divestment Business includes:

(a) the following main tangible assets, to the extent that they are owned by Guidant or other affiliated undertakings of Guidant and relate predominantly to the EVH kits:

(i) manufacturing lines, equipment and other tooling;

(ii) existing inventory of finished products held as at Closing;

(iii) copies of any and all design history files, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, quality control standards and regulatory records;

(iv) any and all models used for training purposes and copies of any and all training materials;

(v) any and all current advertising and promotional materials;

(vi) copies of any and all scientific and medical articles, data results and records of clinical trials, market research reports, studies and data, marketing plans, and other marketing-related information and materials.

(b) the following main intangible assets, to the extent they are owned or licensed by Guidant or affiliated undertakings of Guidant:

(i) the assignment of the VASOVIEW®™, VASOVIEW®™ Uniport and VASOVIEW®™ Hemopro trademarks;

(ii) the assignment of all other intellectual property rights predominantly used in connection with the EVH kits, subject to Guidant receiving a license back insofar as these intellectual property rights are necessary for its retained businesses.

(c) to the extent legally transferable (by way of transfer, assignment or license), all governmental licenses, permits, authorisations and registrations relating exclusively to the EVH kits.

(d) customer lists and credit and other customer records in existence at the date of Closing for the EVH kits.

(e) copies of all books, ledgers and other business records related predominantly to the EVH kits, save that any parts thereof that do not relate to the EVH kits may be redacted from such copies.

(f) at the request of the Purchaser, the Key Personnel and the Personnel predominantly associated with the EVH business.

(g) contracts (or portions thereof), to the extent they relate to the EVH kits, and to the extent they are assignable (however, Guidant is willing to help the Purchaser obtain assignments of or substitutes for these contracts as they relate to the kits).

12. In the event that materials to be transferred contain information that is confidential to Guidant's retained businesses, these shall be redacted as appropriate.

13. For the avoidance of doubt, the Divestment Business does not include manufacturing or warehousing facilities.

14. In order to assist a Purchaser to assume responsibility for manufacturing the EVH kits, at the request of the Purchaser, Guidant will provide technical assistance to the Purchaser regarding the installation, qualification and validation of the transferred manufacturing lines and equipment, on a reasonable cost plus basis to be agreed with the Purchaser and supply the Purchaser with all requirement of the EVH kits during such installation, qualification and validation period on a reasonable cost plus basis to be agreed with the Purchaser.

Annex I-A

List of Guidant's Cardiac Surgery Products

Beating-heart stabilisation systems

Stabilisers/retractors

- AXIUS™ Vacuum 2 Stabiliser with RIGID Feet
- ACROBAT™ Vacuum Stabiliser
- ULTIMA™ Mechanical Stabiliser
- ACROBAT™ Mechanical Stabiliser
- Axius™ Vacuum Tubing Sets
- Activator II Drive Mechanism (Retractor)
- ULTIMA™ ACTIVATOR™ Drive Mechanism (Retractor)
- Standard Blades and Deep Blades

Positioners

- AXIUS™ XPOSE™ Access Device 3
- AXIUS™ XPOSE™ Access Device 4

Beating-heart accessories

- AXIUS™ Coronary Shunts
- AXIUS™ Blower/Mister

MIDCAB stabilisation systems

- ACCESS MV™ Stabiliser (Access Platform, slide mount stabiliser and IMA holder)
- ACCESS MP™ Lift System (Access MP™ Platform, Access MP™ Lift and LIMA Harvesting Tool)

Endoscopic Vessel Harvesting

- VASOVIEW®™ 6 Endoscopic Vessel Harvesting System
- VASOVIEW®™ 4 Endoscopic Vessel Harvesting System

Anastomosis assistance devices

- HEARTSTRING™ Proximal Seal System (includes aortic cutter)
- HEARTSTRING™ Proximal Seal (does not include aortic cutter)

Surgical ablation devices

- Microwave Surgical Ablation System Flex 4™
- Microwave Surgical Ablation Flex 10™
- Microwave Generator for Flex Products

Pipeline products

- [BUSINESS SECRET]
- [BUSINESS SECRET]
- [BUSINESS SECRET]

Schedule II

Cordis' Coronary Steerable Guidewires Business in the EEA

1. This business consists of the assets directly and predominantly used in Cordis' coronary steerable guidewire business in the EEA.

2. The coronary steerable guidewires constituting this business include Cordis' current EEA portfolio of coronary steerable guidewires, as listed in the attached Annex II-A (the "EEA SGW Products").

3. Following paragraph 5 of the Commitments, this Divestment Business includes:

(a) the following main tangible assets:

(i) Cordis' inventory of finished EEA SGW Products held at the date of Closing for sale within the EEA, comprising all inventory already shipped to Cordis' distribution warehouses in the EEA and all inventory held at Johnson & Johnson Health Care Systems, Inc's distribution warehouse in Memphis, Tennessee at the date of Closing that are designated for shipment to the EEA;

(ii) copies of all design history files, technical files, drawings, product specifications, validation documentation, packaging specifications, quality control standards and regulatory records relating predominantly to the EEA SGW Products;

(iii) copies of existing sales and promotion material used in the EEA and related predominantly to the EEA SGW Products;

(iv) copies of all data results and records of clinical trials to the extent relevant to coronary applications of the EEA SGW Products;

(v) copies of all marketing research materials to the extent relevant to the marketing of the EEA SGW Products in the EEA for coronary applications;

(vi) copies of all books, ledgers and other business records to the extent related predominantly to the EEA SGW Products;

(vii) customer lists and credit and other records to the extent relating to EEA customers for the EEA SGW Products for coronary applications in existence at the date of Closing.

(b) the following main intangible assets:

(i) the assignment or the license for use in connection with coronary steerable guidewires of all rights in the EEA of Affiliated Undertakings in or to the following trademarks and registered design rights (including any registrations and applications therefor): (i) ATW™; (ii) ATW and design (iii) REFLEX®; (iv) SHINOBI®; (v) STABILIZER®; (vi) WIZDOM®; (vii) CINCH®; and (viii) EASY TWIST®;

(ii) the grant of a license (including the right to sub-license) limited to the territory of the EEA and limited to the field of use of steerable guidewires for coronary applications of any other intellectual property rights (other than trademarks, the JOHNSON & JOHNSON, J&J and Cordis names and derivatives thereof) that, immediately prior to Closing (i) are owned by J&J, Cordis or Affiliated

Undertakings, or under which J&J, Cordis or Affiliated Undertakings have the right to transfer or grant sublicenses to third parties; and (ii) are used by Cordis in the EEA at the Effective Date in connection with the EEA SGW Products. The license shall be exclusive as against third parties subject to any licenses J&J, Cordis or an Affiliated Undertaking has granted prior to the date of closing of the J&J/Guidant merger; and the license will be exclusive as against J&J for a period of [BUSINESS SECRET] after the Closing. For the avoidance of doubt, J&J shall, in any event, have the right to exploit the intellectual property outside the EEA or outside the field of use of the EEA SGW Products (in the EEA).

(c) to the extent legally transferable (by way of transfer, assignment or license), all EEA governmental licenses, permits, authorisations and registrations relating exclusively to the EEA SGW Products; if such licenses, permits, authorisations or registrations are not legally transferable or do not relate exclusively to the EEA SGW Products, J&J (or the relevant Affiliated Undertaking) shall assist the Purchaser in obtaining an equivalent license, permit, authorisation or registration.

4. In the event that materials to be transferred contain information that is confidential to J&J's retained businesses, these shall be redacted as appropriate.

5. For the avoidance of doubt, the Divestment Business does not include manufacturing, sterilisation or warehousing facilities or equipment.

6. At the request of the Purchaser, J&J and/or Cordis will provide technical assistance necessary for the Purchaser to assume responsibility for the Divestment Business, for an appropriate period of time and on a reasonable cost plus basis to be agreed with the Purchaser.

7. Cordis has a manufacturing agreement with [BUSINESS SECRET] under which [BUSINESS SECRET] manufactures steerable guidewire products for Cordis (the "[BUSINESS SECRET] Agreement"). At the request of the Purchaser, Cordis will use reasonable efforts to assign the [BUSINESS SECRET] Agreement (in relevant part) to the Purchaser or to procure that [BUSINESS SECRET] will enter into a manufacturing agreement with the Purchaser on terms substantially similar to the [BUSINESS SECRET] Agreement. Otherwise, Cordis commits to supply the Purchaser with all its requirements of EEA SGW Products, for an appropriate period of time and on a reasonable cost plus basis to be agreed with the Purchaser.

8. Johnson & Johnson Services, Inc. has an agreement with [BUSINESS SECRET] under which [BUSINESS SECRET] sterilises steerable guidewire products for Cordis (the "[BUSINESS SECRET] Agreement"). At the request of the Purchaser, Cordis will use reasonable efforts to procure the assignment of the [BUSINESS SECRET] Agreement (in relevant part) to the Purchaser or to procure that that [BUSINESS SECRET] will enter into a sterilisation services agreement with the Purchaser on terms substantially similar to the [BUSINESS SECRET] Agreement as it pertains to Cordis.

Annex II-A

List of EEA SGW Products

- ATW All Track Wire
- ATW Marker Wire
- CINCH Extension Wire
- REFLEX
- STABILIZER Balanced Performance Guidewires
- STABILIZER PLUS Guidewire
- STABILIZER Marker Wire
- STABILIZER XS
- SHINOBI Steerable Guidewires
- SHINOBI PLUS Steerable Guidewires
- WIZDOM PTCA Steerable Guidewires
- WIZDOM ST Steerable Guidewires
- EASY TWIST Torque Device

Schedule III

Guidant Endovascular Business in the EEA

1. This business consists of the assets and personnel directly and predominantly included in Guidant's Endovascular Solutions business unit in the EEA.

2. The endovascular devices constituting this business include Guidant's current EEA portfolio of endovascular guiding catheters, endovascular steerable guidewires, PTA balloon catheters, endovascular stents (Bx and Sx) and EPDs, as well as endovascular products in Guidant's pipeline for which a CE Mark submission has already been filed or is expected to be filed, according to current plans, [BUSINESS SECRETS], as listed in the attached Annex III-A (together the "EEA Endo Products").

3. Following paragraph 5 of the Commitments, this Divestment Business includes:

(a) the following main tangible assets:

(i) the transfer of Guidant's inventory of finished EEA Endo Products held at the Closing (which shall not be significantly different in size and composition from that held at the Effective Date), comprising all inventory already shipped to one of Guidant's EEA warehouses and all inventory held at Guidant's Temecula facility that is designated for shipment to the EEA;

(ii) copies of all design history files, technical files, drawings, product specifications, validation documentation, packaging specifications, quality control standards and regulatory records to the extent relating to the EEA Endo Products;

(iii) the transfer of existing sales and promotion material designed for the EEA and used in connection with the EEA Endo Products;

(iv) at the option of the Purchaser, training equipment and software (by way of sale, transfer or license) that are used in connection with the EEA Endo Products, together with copies of training materials that are used in training for the EEA Endo Products;

(v) copies of all data, results and records of clinical trials and marketing research to the extent relevant to the EEA Endo Products, including, in the case of pipeline products, copies of all R&D and other materials, in a form readily intelligible to the Purchaser, held by J&J that are needed by the Purchaser to introduce those pipeline products in the EEA;

(vi) copies of all books, ledgers and other business records to the extent relating to the EEA Endo Products;

(vii) customer lists and credit and other records relating to EEA customers for the EEA Endo Products in existence at the date of Closing.

(b) the following main intangible assets:

(i) the assignment or the license for use in connection with endovascular devices of all rights in the EEA of Guidant or affiliated undertakings of Guidant in the following trademarks and registered design rights (including any registrations and applications therefor): (A) VERIPATH™; (B) HI-TORQUE SUPRA

CORE™; (C) HI-TORQUE STEEL CORE™; (D) HI-TORQUE SPARTACORE™; (E) HI-TORQUE MEMCORE™; (F) AGILTRAC™; (G) RX VIATRAC™; (H) OMNILINK™; (I) DYNALINK®; (J) HERCULINK™; (K) HERCULINK ELITE™; (L) ABSOLUTE™; (M) RX ACCULINK®; (N) RX ACCUNET™; (O) RX ACCUNET 2™;

(ii) the grant of a license (including (A) the right to make improvements and (B) the right to sub-license) limited to the territory of the EEA and limited to the field of use of endovascular devices, of any other intellectual property rights (other than trademarks, the Guidant name and derivatives thereof) that, immediately prior to Closing, (I) are owned by Guidant or affiliated undertakings of Guidant, or under which Guidant or its affiliated undertakings have the right to transfer or grant sublicenses to third parties, and (II) are used by Guidant in the EEA at the date of Closing in connection with the EEA Endo Products. Such license shall be exclusive as against third parties, but shall be subject to any licenses Guidant has granted prior to the date of closing of the J&J/Guidant merger; the license shall be non-exclusive as against J&J (i.e., J&J will be able to exploit the intellectual property itself) if J&J had the right to exploit the intellectual property prior to the J&J/Guidant merger; otherwise the license will be exclusive as against J&J for a period of [BUSINESS SECRET] after the Closing. For the avoidance of doubt, (III) J&J shall, in any event, have the right to exploit the intellectual property outside the EEA or outside the field of the EEA Endo Products (in the EEA) and (IV) the Purchaser shall be free to use the intellectual property rights described in this paragraph as it sees fit within the territory of the EEA and within the field of use of endovascular devices.

(c) to the extent legally transferable (by way of transfer, assignment or license), all EEA licenses, permits and other governmental authorisations and registrations relating predominantly to the EEA Endo Products; if such licenses, permits, authorisations or registrations are not legally transferable or do not predominantly relate to EEA Endo Products, J&J (or an Affiliated Undertaking) shall assist the Purchaser in obtaining an equivalent license, permit, authorisation or registration.

(d) at the request of the Purchaser, the Key Personnel identified in Annex III-B.

(e) at the request of the Purchaser, the Personnel associated predominantly with the Divestment Business; a list of personnel associated predominantly with the Divestment Business as at 1 April 2005 is attached at Annex III-C.

4. In the event that materials to be transferred contain information that is confidential to J&J's retained businesses, these shall be redacted as appropriate.

5. For the avoidance of doubt, the Divestment Business does not include manufacturing, sterilisation or warehousing facilities or equipment.

6. In order to assist a Purchaser to assume responsibility for manufacturing the EEA Endo Products, at the request of the Purchaser, J&J will provide technical assistance (including appropriate training of the Purchaser's employees) required by the Purchaser regarding the construction, installation, qualification and validation of suitable manufacturing equipment and facilities, on a reasonable cost plus basis to be agreed with the Purchaser. The term of the technical assistance agreement shall be [BUSINESS SECRET] from Closing. An extension of the [BUSINESS SECRET] term may be requested by J&J and/or the

Purchaser, based on a reasoned request showing good cause and accompanied by a report from the Monitoring Trustee.

7. The technical assistance agreement referred to in paragraph 6 will include appropriate provisions designed to incentivise J&J to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time.

8. At the request of the Purchaser, J&J will provide the Purchaser with contract manufacturing services for the Purchaser's requirements of the EEA Endo Products on terms consistent with the principles set out in Annex III-D for a period of up to [BUSINESS SECRET] from Closing, and thereafter on normal OEM commercial terms. In the event that the technical assistance agreement is extended in accordance with paragraph 6 above, J&J will continue to supply EEA Endo Products on the terms initially agreed, unless it is shown that the Purchaser's inability to assume responsibility for the manufacture of the EEA Endo Products at the date [BUSINESS SECRET] from Closing is attributable to a delay on the part of the Purchaser in making use of the technical assistance offered by J&J pursuant to paragraph 6 above.

9. J&J shall provide the Purchaser with clinical research and data relating to the pipeline products, presented in a form readily intelligible to the Purchaser. J&J shall provide assistance to the Purchaser for the interpretation and the proper application and development of the research and data mentioned in this paragraph. J&J shall also share with the Purchaser any other data or research it may subsequently develop with respect to the pipeline products.

10. The technical assistance agreement referred to in paragraph 6 and the supply agreement referred to in paragraph 8 will include the Fast Track Resolution Procedure provisions set out in paragraphs 36 to 38 of the Commitments.

Annex III-A

List of EEA Endo Products

Endovascular guiding catheters

- Veripath guiding catheters

Endovascular steerable guidewires

- Hi-Torque Supra-Core .035” steerable guidewires
- Hi-Torque Steel-Core .018” steerable guidewires
- Hi-Torque SpartaCore .014” steerable guidewires
- Hi-Torque MemCore Firm .014” steerable guidewires

PTA balloon catheters

- Agiltrac peripheral dilatation catheters
- RX Viatrac Plus peripheral dilatation catheters

Stents

- Omnilink peripheral stent systems (Bx)
- Dynalink peripheral self-expanding stent systems (non-carotid Sx)
- RX Herculink peripheral stent systems (Bx marketed for renal indications)
- Absolute peripheral self-expanding stent systems (non-carotid Sx)
- RX Acculink carotid stent systems (carotid Sx)

Embolic Protection Devices

- RX Accunet embolic protection devices
- RX Accunet 2 embolic protection devices

[…]* Pipeline products, according to current plans

- [BUSINESS SECRET]
- [BUSINESS SECRET]
- [BUSINESS SECRET]

Annex III-B

List of Key Personnel

- [BUSINESS SECRET]
- [BUSINESS SECRET]
- [BUSINESS SECRET]

Annex III-C

[…]* List of Personnel associated predominantly with the Divestment Business as at 1 April 2005

[BUSINESS SECRET]

Annex III-D

Supply Agreement Principles

- The supply agreement will cover one or more of the EEA Endo Products listed in Annex III-A, the precise range of products to be determined at the request of the Purchaser. The agreement will include appropriate provisions allowing the Purchaser to withdraw specific EEA Endo Products from the scope of the agreement, so allowing it to self-manufacture or to source from a different supplier.
- During the [BUSINESS SECRET] after the Closing (or longer in the circumstances described in paragraphs 6 and 8 of this Schedule), J&J will sell EEA Endo Products to the Purchaser on a reasonable cost plus-margin basis. Cost shall be defined in accordance with Generally Acceptable Accounting Principles and negotiated by J&J and the Purchaser at a level consistent with standard industry practice; margin shall be set at a discount to standard industry practice.
- After the [BUSINESS SECRET] (or longer in the circumstances described in paragraphs 6 and 8 of this Schedule), the agreement may be extended at the request of the Purchaser, but will then be governed by normal OEM conditions.
- All EEA Endo Products supplied by J&J to the Purchaser shall be sterilised prior to dispatch.
- J&J shall be required to provide support to the Purchaser in its application for product approval from the competent regulatory body within the EEA, and in particular shall provide to the Purchaser or the regulatory body such information as is requested by that body.
- The supply agreement shall include appropriate provisions with regard to regulatory compliance.
- The Purchaser shall be required to send J&J non-binding 12 month rolling monthly forecasts of its reasonably expected requirements of EEA Endo Products (firm and binding as to the next two months). If, for any reason (e.g. production shortages or events akin to force majeure), J&J is unable to meet the Purchaser's requirements of a particular EEA Endo Product, J&J shall allocate deliveries of that product to the Purchaser in the proportion that represents [BUSINESS SECRET] % of the proportion that prevailed between J&J and the Purchaser on average during the two preceding completed quarters.
- The Purchaser may terminate the supply agreement at its discretion on [BUSINESS SECRET] notice.
- Delivery of the EEA Endo Products will be made in a timely manner and according to a pre-defined schedule, in line with standard industry practice.

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EUROPEAN COMMISSION
Competition DG

Policy and Strategic Support

OPINION

of the ADVISORY COMMITTEE on CONCENTRATIONS
given at its 134th meeting on 9 August 2005
concerning a draft decision relating to
Case COMP/M.3687– Johnson & Johnson/Guidant

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1. The Advisory Committee agrees with the Commission that the notified operation constitutes a concentration within the meaning of Article 1(3) and 3(1)(b) of the EC Merger Regulation and that it has a Community dimension as defined by that Regulation.

2. The Advisory Committee agrees with the Commission that for the purpose of assessing the present operation, the **relevant product markets** are
   in interventional cardiology (IC) devices:
   a) Drug-eluting stents (DES)
   b) Bare metal stents (BMS)
   c) Coronary guiding catheters
   d) Percutaneous transluminal coronary angioplasty (PTCA) balloon catheters
   e) Steerable guidewires (SGW)
   in endovascular devices:
   f) Endovascular guiding catheters
   g) Steerable guidewires (SGW)
   h) Percutaneous transluminal angioplasty (PTA) balloon catheters
   i) Embolic protection devices (EPD)
   j) Balloon expandable stents (BX)
   k) Self expandable carotid stents (SX carotid stents)
   l) Self expandable non-carotid stents (SX non-carotid stents)
   in cardiac surgery devices:
   m) Beating-heart surgery systems
   n) Blowers and misters
   o) Endoscopic vessel harvesting systems (EVH).

3. The Advisory Committee agrees with the Commission that for the purpose of assessing the present operation, the **relevant geographic markets** are **national** for all of the above mentioned product markets.

4. A majority of the Advisory Committee agrees with the Commission that the proposed concentration does **not significantly impede effective competition** in the common market or in a substantial part of it (within the meaning of Article 2(2) of the Merger Regulation) and the EEA for the following markets
   in interventional cardiology (IC) devices:
   a) Drug-eluting stents (DES)
   b) Bare metal stents (BMS)
   c) Coronary guiding catheters
   d) Percutaneous transluminal coronary angioplasty (PTCA) balloon catheters
   in endovascular devices:

e) Endovascular guiding catheters
f) Steerable guidewires (SGW)
g) Percutaneous transluminal angioplasty (PTA) balloon catheters
h) Embolic protection devices (EPD)

in cardiac surgery devices:

i) Beating-heart surgery systems
j) Blowers and misters.

A minority of the Advisory Committee disagrees.

5. The Advisory Committee agrees with the Commission that the proposed concentration is likely to result in a **significant impediment to effective competition** in the common market or in a substantial part of it and the EEA

in interventional cardiology (IC) devices:

a) as a result of the strengthening of Guidant's dominant postition in the market for **steerable guidewires (SGW)**

in endovascular devices:

b) in particular as a result of the creation of a dominant position in the national markets of Austria, Belgium, France, Germany, Italy, Luxembourg, the Netherlands, Portugal and Spain for **balloon expandable stents (BX)**
c) in particular as a result of the creation of a dominant position, as the proposed concentration will give rise to non-coordinated adverse effects in the national markets of Austria, Belgium, France, Finland, Germany, Italy, Luxembourg, the Netherlands, Portugal and Spain for **self expandable carotid stents (SX carotid stents)**
d) in particular as a result of the creation or the strengthening of a dominant position, as the proposed concentration will give rise to non-coordinated adverse effects in the national markets of Austria, Belgium, Germany, and the Netherlands for **self expandable non-carotid stents (SX non-carotid stents)**

in cardiac surgery devices:

e) as the concentration will give rise to a dominant position in the market for **Endoscopic vessel harvesting systems (EVH)**.

6. A majority of the Advisory Committee agrees with the Commission that the **commitments** are sufficient to remove the significant impediments to competition on the markets for
   a) Coronary steerable guidewires (SGW)
   b) Balloon expandable stents (BX)
   c) Self expandable carotid stents (SX carotid stents)
   d) Self expandable non-carotid stents (SX non-carotid stents)
   e) Endoscopic vessel harvesting systems (EVH).

   A minority of the Advisory Committee disagrees.

7. A majority of the Advisory Committee agrees with the Commission that, subject to full compliance with the undertakings offered by the parties, the proposed concentration does not significantly impede effective competition in the common market or a substantial part of it, in particular as a result of the creation or strengthening of a dominant position, within the meaning of Article 2(2) of the Merger Regulation and that the proposed concentration is therefore to be declared compatible with Article 2(2) and 8(2) of the Merger Regulation and Article 57 of the EEA Agreement.

   A minority of the Advisory Committee disagrees.

8. The Advisory Committee asks the Commission to take into account all the other points raised during the discussion.

BELGIË/BELGIQUE	**ČESKÁ REPUBLIKA**	**DANMARK**	**DEUTSCHLAND**	**EESTI**
J. MUTAMBA	L. BRINEK	---	B. KRUEGER	---
ELLADA	**ESPAÑA**	**FRANCE**	**IRELAND**	**ITALIA**
---	---	O. HÉRY	---	L. RAZZITTI
KYPROS/KIBRIS	**LATVIJA**	**LIETUVA**	**LUXEMBOURG**	**MAGYARORSZÁG**
---	---	---	---	---
MALTA	**NEDERLAND**	**ÖSTERREICH**	**POLSKA**	**PORTUGAL**
---	---	A. LUKASCHEK	---	---
SLOVENIJA	**SLOVENSKO**	**SUOMI-FINLAND**	**SVERIGE**	**UNITED KINGDOM**
---	---	J. BOËLIUS	C. BERGER	R. NIETO

EUROPEAN COMMISSION

The Hearing Officer

FINAL REPORT OF THE HEARING OFFICER IN CASE COMP/M.3687 – JOHNSON & JOHNSON / GUIDANT

(pursuant to Articles 15 and 16 of Commission Decision (2001/462/EC, ECSC) of 23 May 2001 on the terms of reference of Hearing Officers in certain competition proceedings – OJ L162, 19.06.2001, p.21)

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

At the end of the first phase of the investigation, the Commission concluded that the concentration raised serious doubts as to its compatibility with the common market and with the EEA Agreement. On 22 April 2005, the Commission therefore initiated proceedings in accordance with Article 6(1)(c) of the Merger Regulation.

A statement of objections was sent to J&J on 20 June 2005. The following day, access to the Commission's file was granted. J&J was asked to reply by 27 June 2005. This deadline was complied with.

The parties did not request the opportunity to develop their arguments in a formal oral hearing.

Edwards Lifesciences SA, Sorin SpA, Abott Laboratories and Medtronic Inc were admitted as interested third parties according to Article 18(4) of the Merger Regulation. They were informed of the nature and subject matter of the case, as appropriate.

On 13 July 2005, J&J offered commitments in order to resolve the competition concerns identified in the Statement of Objections. A market test of the commitments was carried out. I have not been asked to verify the objectivity of the market enquiry. The parties did not request further access to the Commission's file, in particular the results of the market test.

In the light of the commitments proposed and having analysed the results of the market test, the draft decision concludes that the proposed concentration is compatible with the common market and with the EEA Agreement.

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Office: J-79-05/215 - Telephone: direct line (+32-2) 296.55.75. - Fax: (+32-2) 296.95.78.

I consider that the rights to be heard of all participants to the present proceeding have been respected.

Brussels, 10 August 2005.

(signed)
Karen WILLIAMS